

US3272026 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:18:59

All time stamps listed in this document are displayed in GMT

US3272026

Form: Participant Creation

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

Participant ID

US3272026

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

US3272026

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

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

Visit date (dd MMM yyyy)	01 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3272026

Folder: Screening

Form: Demographics

Data signed: (b) (4) 29 Apr 2021 16:56:32

Generated On: 09 Jun 2021 16:18:59

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	46
Age Units	YEARS
Age (Derived)	46
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 29 Apr 2021 16:56:33

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Date of Informed Consent (<i>dd MMM yyyy</i>)	01 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 29 Apr 2021 16:56:33

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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) 29 Apr 2021 16:56:33

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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) 29 Apr 2021 16:56:33

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Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Apr 2021 16:56:33

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Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Apr 2021 16:56:33

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 16:56:33

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 AUG 2020
Time of assessment (00:00-23:59)	08:47 (24 HR)
Vital Signs Date and Time (derived)	01 AUG 2020 08:47
Height (xxx.x)	185.0 cm
Weight (xxx.x)	123.2 kg
BMI (xxx.x)	35.99708 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 16:56:33

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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: Screening

Form: Risk of Exposure

Data signed: (b) (4) 29 Apr 2021 16:56:33

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 29 Apr 2021 16:56:33

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

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

Visit date (dd MMM yyyy)	01 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 29 Apr 2021 16:56:33

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What was the date of randomization? (dd MMM yyyy) 01 AUG 2020

What was the participant's randomization number? 100363

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 29 Apr 2021 16:56:33

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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) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 AUG 2020
Time of assessment (00:00-23:59)	08:47 (24 HR)
Vital Signs Date and Time (derived)	01 AUG 2020 08:47
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 AUG 2020
Time of assessment (00:00-23:59)	10:42 (24 HR)
Vital Signs Date and Time (derived)	01 AUG 2020 10:42
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	100 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 16:56:33

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 16:56:33

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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) 01 AUG 2020

What was the treatment time? (00:00-23:59) 10:10 (24 HR)

Treatment Date and Time (derived) 01 AUG 2020 10:10

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) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

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

Collection date (dd MMM yyyy)	01 AUG 2020
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Collection time (00:00-23:59)	09:26 (24 HR)
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Collection date and time (derived)	01 AUG 2020 09:26
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

Collection date (dd MMM yyyy)			01 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:20	01 AUG 2020 09:20
Nasopharyngeal Swab 2	No		

US3272026

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

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: 09 Jun 2021 16:18:59

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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 AUG 2020 10:50

PC Open Date & Time

01 AUG 2020 10:30

PC Close Date & Time

01 AUG 2020 13:00

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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 98.2 °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	02 AUG 2020 01:03
PC Open Date & Time	01 AUG 2020 13:55
PC Close Date & Time	02 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

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

97.3 °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 AUG 2020 22:06

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 21:07

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 20:41

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 21:26

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

06 AUG 2020 18:56

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 17:26

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

01 AUG 2020 10:50

PC Open Date & Time

01 AUG 2020 10:30

PC Close Date & Time

01 AUG 2020 13:00

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

02 AUG 2020 01:04

PC Open Date & Time

01 AUG 2020 13:55

PC Close Date & Time

02 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

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

02 AUG 2020 22:07

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

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

03 AUG 2020 21:08

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

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

04 AUG 2020 20:41

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

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

05 AUG 2020 21:26

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

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

06 AUG 2020 18:56

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

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

07 AUG 2020 17:26

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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 ☐

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

No ☒

Yes ☐

PC Time stamp	01 AUG 2020 10:51
PC Open Date & Time	01 AUG 2020 10:30
PC Close Date & Time	01 AUG 2020 13:00

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Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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 ☐

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

No ☒

Yes ☐

PC Time stamp	02 AUG 2020 01:04
PC Open Date & Time	01 AUG 2020 13:55
PC Close Date & Time	02 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 22:08
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 21:08
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

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 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 20:41
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

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)

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 21:27
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

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)

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 18:57
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

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 ☒

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 17:27
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3272026

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 16:56:32

Generated On: 09 Jun 2021 16:18:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3272026

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:56:32

Generated On: 09 Jun 2021 16:18:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 16:56:17

Generated On: 09 Jun 2021 16:18:59

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3272026

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:56:17

Generated On: 09 Jun 2021 16:18:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 16:56:32

Generated On: 09 Jun 2021 16:18:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3272026

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:56:17

Generated On: 09 Jun 2021 16:18:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 10:26
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 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)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 12:05
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3272026

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 11:33 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 11:33

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

US3272026

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

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

Collection date (dd MMM yyyy)	8 SEP 2020
-------------------------------	------------

Collection time (00:00-23:59)	10:46 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	8 SEP 2020 10:46
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US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:36	8 SEP 2020 10:36
Nasopharyngeal Swab 2	No		

US3272026

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 12:05

PC Open Date & Time

08 SEP 2020 11:53

PC Close Date & Time

08 SEP 2020 14:23

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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 97.5 °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	08 SEP 2020 20:25
PC Open Date & Time	08 SEP 2020 15:18
PC Close Date & Time	09 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 16:02

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 23:40

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

11 SEP 2020 15:25

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:12

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 12:01

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

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

98.1 °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

14 SEP 2020 18:46

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

08 SEP 2020 12:09

PC Open Date & Time

08 SEP 2020 11:53

PC Close Date & Time

08 SEP 2020 14:23

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

08 SEP 2020 20:26

PC Open Date & Time

08 SEP 2020 15:18

PC Close Date & Time

09 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

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

09 SEP 2020 16:03

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

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

10 SEP 2020 23:40

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

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

11 SEP 2020 15:26

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

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

12 SEP 2020 12:12

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

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

13 SEP 2020 12:01

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

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

14 SEP 2020 18:46

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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 ☐

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 12:09
PC Open Date & Time	08 SEP 2020 11:53
PC Close Date & Time	08 SEP 2020 14:23

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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 ☐

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 20:27
PC Open Date & Time	08 SEP 2020 15:18
PC Close Date & Time	09 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 16:03
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 23:41
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

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 ☒

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 15:26
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

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

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:02
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

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 ☒

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 18:46
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3272026

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 16:56:32

Generated On: 09 Jun 2021 16:18:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3272026

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:56:32

Generated On: 09 Jun 2021 16:18:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 16:56:32

Generated On: 09 Jun 2021 16:18:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3272026

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:56:32

Generated On: 09 Jun 2021 16:18:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 16:56:32

Generated On: 09 Jun 2021 16:18:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3272026

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:56:32

Generated On: 09 Jun 2021 16:18:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

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

Visit date (dd MMM yyyy)	9 OCT 2020
--------------------------	------------

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

Folder OID	VISIT3
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US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 OCT 2020
Time of assessment (00:00-23:59)	12:53 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 12:53
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3272026

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 OCT 2020

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

US3272026

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

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

Collection date (dd MMM yyyy)	9 OCT 2020
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Collection time (00:00-23:59)	13:05 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	9 OCT 2020 13:05
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US3272026

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:56:33

Generated On: 09 Jun 2021 16:18:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

01 OCT 2020 06:25:56

Patient Cloud Open Date & Time

01 OCT 2020 00:01

Patient Cloud Close Date & Time

05 OCT 2020 23:59

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 OCT 2020 07:53:24

Patient Cloud Open Date & Time

08 OCT 2020 00:01

Patient Cloud Close Date & Time

12 OCT 2020 23:59

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 OCT 2020 10:37:14
Patient Cloud Open Date & Time	15 OCT 2020 00:01
Patient Cloud Close Date & Time	19 OCT 2020 23:59

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 OCT 2020 07:11:00
Patient Cloud Open Date & Time	29 OCT 2020 00:01
Patient Cloud Close Date & Time	02 NOV 2020 23:59

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 09:42:19
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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	12 NOV 2020 11:45:31
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 113
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	False
Muscle aches	True
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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	19 NOV 2020 08:40:43
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

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

Date and time of submission

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 JAN 2021 08:21:38
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	True
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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	28 JAN 2021 18:01:07
Patient Cloud Open Date & Time	25 JAN 2021 00:01
Patient Cloud Close Date & Time	29 JAN 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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

01 FEB 2021 14:37:41

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 07:47:01
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 09:45:51

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 10:18:01

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 12:01:38

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 MAR 2021 19:05:05

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 12:42:27

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 10:14:59

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 12:14:41

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3272026

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:18:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 12:01:52

US3272026

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 16:56:32

Generated On: 09 Jun 2021 16:18:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3272026

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:56:32

Generated On: 09 Jun 2021 16:18:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 16:56:17

Generated On: 09 Jun 2021 16:18:59

Was Contact Attempted? Yes ☐
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

SUBJECT WAS INTUBATED AND
SEDATED. UNABLE TO
COMMUNICATE.

If Contact Not Made, please provide Comments

US3272026

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:56:17

Generated On: 09 Jun 2021 16:18:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 16:56:17

Generated On: 09 Jun 2021 16:18:59

Was Contact Attempted? Yes ☐
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

UNABLE TO COMMUNICATE.
SEDATED AND INTUBATED.

If Contact Not Made, please provide Comments

US3272026

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:56:17

Generated On: 09 Jun 2021 16:18:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3272026

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 16:56:17

Generated On: 09 Jun 2021 16:18:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3272026

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 16:56:17

Generated On: 09 Jun 2021 16:18:59

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Date of Contact	11 NOV 2020
Time of Contact	14:19
Date and Time of Contact (derived)	11 NOV 2020 14:19
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	9 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (5)

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Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

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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 ☐

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Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	101.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

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 ☐

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	80 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	103.1 F
-------------	---------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	18 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	94 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	100.2 F
-------------	---------

Chills	None <input type="checkbox"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>

Cough	None <input type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>

Shortness of Breath	None <input type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>

Difficulty Breathing	None <input type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	19 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	20 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	21 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	90 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98 F
-------------	------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	22 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	90 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.9 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	23 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	68 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.3 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 29 Apr 2021 16:56:13

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	99.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (17)

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 29 Apr 2021 16:56:13

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Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 NOV 2020	
Assessment Not Done	False	
O2 Saturation	81 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (18)

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (18)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 NOV 2020	
Assessment Not Done	False	
O2 Saturation	64 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (19)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (19)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (20)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (20)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 NOV 2020	
Assessment Not Done	False	
O2 Saturation	77 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (20)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (20)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (21)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input checked="" type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (21)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	28 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (21)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input checked="" type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	29 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Form: Symptom Log (22)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input checked="" type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	30 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input checked="" type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	01 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	94 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.4 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Vomiting	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input checked="" type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input checked="" type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	02 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (26)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input checked="" type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	03 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input checked="" type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	04 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Form: Symptom Log (27)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input checked="" type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (28)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	05 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Form: Symptom Log (28)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (28)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input checked="" type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (29)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	6 DEC 2020
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input checked="" type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	07 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (30)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (31)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input checked="" type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (31)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	08 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Form: Symptom Log (31)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input checked="" type="checkbox"/>

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Form: Symptom Log (32)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	09 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Form: Symptom Log (32)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (33)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input checked="" type="radio"/>
	Day 34	<input type="radio"/>
	Day 35	<input type="radio"/>
	Day 36	<input type="radio"/>
	Day 37	<input type="radio"/>
	Day 38	<input type="radio"/>
	Day 39	<input type="radio"/>
	Day 40	<input type="radio"/>

Date	15 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (33)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (33)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (34)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (34)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input checked="" type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	22 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (35)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (35)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input checked="" type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	28 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Form: Symptom Log (35)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (36)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input checked="" type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	5 JAN 2021
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (37)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (37)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input checked="" type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 JAN 2021
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (38)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (38)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input checked="" type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 JAN 2021	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input checked="" type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (39)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input checked="" type="checkbox"/>

Date	10 FEB 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>

Cough	None <input checked="" type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>

Shortness of Breath	None <input checked="" type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>
	Not Done <input type="checkbox"/>

Difficulty Breathing	None <input checked="" type="checkbox"/>
	Mild <input type="checkbox"/>
	Moderate <input type="checkbox"/>
	Severe <input type="checkbox"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Date of Visit	12 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	12 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date _____ 16 NOV 2020

End Date _____

Oxygen Saturation _____ 64 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☒ No ☐

Start Date _____ 16 NOV 2020

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☒ No ☐

Start Date _____ 16 NOV 2020

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Apr 2021 16:56:13

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If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date

End Date

Mechanical Ventilation? Yes ☒ No ☐

Start Date

28 NOV 2020

End Date

25 JAN 2021

ECMO? Yes ☒ No ☐

Start Date

01 DEC 2020

End Date

01 JAN 2021

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☒ No ☐

Start Date

16 NOV 2020

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☒
No ☐

Start Date

30 NOV 2020

Evidence of Pneumonia:

Clinical Evidence Yes ☒
No ☐

Date of Assessment

16 NOV 2020

Radiographical Evidence Yes ☒
No ☐

Date of Assessment

16 NOV 2020

Admission to an intensive care unit due to SARS-CoV-2 Yes ☒
No ☐

Start Date

16 NOV 2020

End Date

12 FEB 2021

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 13:10
Height (xxx.x)	178 cm
Weight (xxx.x)	122.9 kg
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 NOV 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: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

12 NOV 2020

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Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

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 SICKD28

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

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: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

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

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

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

Visit date (dd MMM yyyy)	25 MAR 2021
--------------------------	-------------

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

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

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

Date of updated informed consent (dd MMM yyyy)	25 MAR 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (dd MMM yyyy)	25 MAR 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

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

Collection date (dd MMM yyyy)	25 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	13:19 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	25 MAR 2021 13:19
------------------------------------	-------------------

US3272026

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 MAR 2021

Collection time (00:00 - 23:59)

13:31

Collection Date and Time (derived)

25 MAR 2021 13:31

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Nov 2020 00:48:06

Generated On: 09 Jun 2021 16:18:59

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) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID	USA-US070-2020-MRNA-1273-P30 1000019
Adverse event	COVID19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	08 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	20 JAN 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

Number of Days in ICU	20
Persistent or significant disability or incapacity	True
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	ONGOING SUPPLEMENTAL O2 NEEDS. 1L/NC AT REST, 3L/NC C ACTIVITY, 2L/NC AT NIGHT. CONTINUING WITH PT FOR STRENGTHENING.

Narrative

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

ADMITTED FOR ARDS D/T
COVID-19 VIRUS. DIAGNOSED
WITH COVID PNEUMONIA IN
MID-NOVEMBER 2020 AND
SUBSEQUENTLY DEVELOPED
RESPIRATORY FAILURE D/T
ASSOCIATED ARDS AND
REQUIRED EMERGENT
INTUBATION AT THE END OF
THE MONTH DUE TO SEVERE
HYPOXIA. DESPITE MAXIMAL
VENT SETTINGS, THE PATIENT
COULD NOT MAINTAIN
ADEQUATE OXYGEN
SATURATION AND WAS SENT
TO A REGIONAL HOSPITAL AT
THE BEGINNING OF DECEMBER
FOR EVALUATION FOR VV
ECMO. PARTICIPANT WAS
CANNULATED AND
EVENTUALLY REQUIRED
TRACHEOSTOMY D/T
PRLONGED VENTILATION
REQUIREMENTS. ECMO WAS
DECANNULATED 01JAN2021.
HOSPITAL COURSE WAS
COMPLICATED BY VRE
BACTEREMIA, TRACH SITE
BLEEDING, EPISTAXIS AND
THROMBOCYTOPENIA WITH
BOTH HEME/ONC AND ID ON
BOARD. PARTICIPANT
SEROTONIN RELEASE ASSAY IS
NEGATIVE MAKING HIT LESS
LIKELY. PARTICIPANT

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

COMPLETED ANTIBIOTICS AND
WAS STARTED ON
PREDNISONE WITH CONCERN
CAP. ON PREDNISONE TAPER
WITH BACTRIM ON BOARD.
DISMISSED TO LOCAL REHAB
FACILITY WHERE HE HAD
HEMORRHAGING FROM HIS
TRACHEA AND WAS
TRANSFERRED BACK FOR
EVALUATION. HEMORRHAGE
RESOLVED WITHOUT
INTERVENTION,
TRACHEOSTOMY
DECANNULATION 25JAN2021.
TUBE FEEDINGS STOPPED AS
PO RESUMED. TRANSFERRED
BACK TO REHAB.
SUPPLEMENTAL 1-3L/NC WITH
ACTIVITY. DISCHARGED HOME
11FEB2021.

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 (2)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID	USA-US070-2020-MRNA-1273-P30 1000019
Adverse event	MULTIFOCAL PNEUMONIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	16 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	20 JAN 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

Number of Days in ICU	28
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	PARTICIPANT RETURNED HOME. REMAINS ON 1L/NC AT REST, 3L/NC WITH ACTIVITY, AND 2L/NC HS.

Narrative

US3272026

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

ADMITTED FOR ARDS D/T
COVID-19 VIRUS. DIAGNOSED
WITH COVID PNEUMONIA IN
MID-NOVEMBER 2020 AND
SUBSEQUENTLY DEVELOPED
RESPIRATORY FAILURE D/T
ASSOCIATED ARDS AND
REQUIRED EMERGENT
INTUBATION AT THE END OF
THE MONTH DUE TO SEVERE
HYPOXIA. DESPITE MAXIMAL
VENT SETTINGS, THE PATIENT
COULD NOT MAINTAIN
ADEQUATE OXYGEN
SATURATION AND WAS SENT
TO A REGIONAL HOSPITAL AT
THE BEGINNING OF DECEMBER
FOR EVALUATION FOR VV
ECMO. PARTICIPANT WAS
CANNULATED AND
EVENTUALLY REQUIRED
TRACHEOSTOMY D/T
PRLONGED VENTILATION
REQUIREMENTS. ECMO WAS
DECANNULATED 01JAN2021.
HOSPITAL COURSE WAS
COMPLICATED BY VRE
BACTEREMIA, TRACH SITE
BLEEDING, EPISTAXIS AND
THROMBOCYTOPENIA WITH
BOTH HEME/ONC AND ID ON
BOARD. PARTICIPANT
SEROTONIN RELEASE ASSAY IS
NEGATIVE MAKING HIT LESS
LIKELY. PARTICIPANT

US3272026

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

COMPLETED ANTIBIOTICS AND
WAS STARTED ON
PREDNISONE WITH CONCERN
CAP. ON PREDNISONE TAPER
WITH BACTRIM ON BOARD.
DISMISSED TO LOCAL REHAB
FACILITY WHERE HE HAD
HEMORRHAGING FROM HIS
TRACHEA AND WAS
TRANSFERRED BACK FOR
EVALUATION. HEMORRHAGE
RESOLVED WITHOUT
INTERVENTION,
TRACHEOSTOMY
DECANNULATION 25JAN2021.
TUBE FEEDINGS STOPPED AS
PO RESUMED. TRANSFERRED
BACK TO REHAB.
SUPPLEMENTAL 1-3L/NC WITH
ACTIVITY. DISCHARGED TO
HOME 11FEB2021.

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

US3272026

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID

Adverse event

ACUTE KIDNEY INJURY

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)

16 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)

30 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

PARTICIPANT WAS ADMITTED
TO THE HOSPITAL ON
16NOV2020 FOR ACUTE
HYPOXIC RESPIRATORY
FAILURE SECONDARY TO ARDS
FROM COVID-19. AKI WAS
FOUND INCIDENTALLY VIA
LABORATORY RESULTS.
CREATININE 16NOV2020 WAS
1.64 AND 17NOV2020 WAS 1.42.
PARTICIPANT WAS TREATED
WITH GENTLE HYDRATION X
48 HOURS FOLLOWED BY
FUROSEMIDE DAILY.

CREATININE LEVELS:
16NOV2020: 1.64
17NOV2020: 1.42
25NOV2020: 1.38
26NOV2020: 1.21
28NOV2020: 0.93
30NOV2020: NEPHROLOGY
CONSIDERS AKI RESOLVED
AND SIGNS OFF.

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)	

US3272026

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID	USA-US070-2020-MRNA-1273-P30 1000019
Adverse event	ACUTE RESPIRATORY FAILURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	16 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	20 JAN 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

Number of Days in ICU	28
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	INCREASED O2 NEEDS: BASELINE- 1L/NC HS- 2L/NC ACTIVITY- 3L/NC

Narrative

US3272026

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

ADMITTED FOR ARDS D/T
COVID-19 VIRUS. DIAGNOSED
WITH COVID PNEUMONIA IN
MID-NOVEMBER 2020 AND
SUBSEQUENTLY DEVELOPED
RESPIRATORY FAILURE D/T
ASSOCIATED ARDS AND
REQUIRED EMERGENT
INTUBATION AT THE END OF
THE MONTH DUE TO SEVERE
HYPOXIA. DESPITE MAXIMAL
VENT SETTINGS, THE PATIENT
COULD NOT MAINTAIN
ADEQUATE OXYGEN
SATURATION AND WAS SENT
TO A REGIONAL HOSPITAL AT
THE BEGINNING OF DECEMBER
FOR EVALUATION FOR VV
ECMO. PARTICIPANT WAS
CANNULATED AND
EVENTUALLY REQUIRED
TRACHEOSTOMY D/T
PRLONGED VENTILATION
REQUIREMENTS. ECMO WAS
DECANNULATED 01JAN2021.
HOSPITAL COURSE WAS
COMPLICATED BY VRE
BACTEREMIA, TRACH SITE
BLEEDING, EPISTAXIS AND
THROMBOCYTOPENIA WITH
BOTH HEME/ONC AND ID ON
BOARD. PARTICIPANT
SEROTONIN RELEASE ASSAY IS
NEGATIVE MAKING HIT LESS
LIKELY. PARTICIPANT

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

COMPLETED ANTIBIOTICS AND
WAS STARTED ON
PREDNISONE WITH CONCERN
CAP. ON PREDNISONE TAPER
WITH BACTRIM ON BOARD.
DISMISSED TO LOCAL REHAB
FACILITY WHERE HE HAD
HEMORRHAGING FROM HIS
TRACHEA AND WAS
TRANSFERRED BACK FOR
EVALUATION. HEMORRHAGE
RESOLVED WITHOUT
INTERVENTION,
TRACHEOSTOMY
DECANNULATION 25JAN2021.
TUBE FEEDINGS STOPPED AS
PO RESUMED. DISCHARGED
HOME 12FEB2021. INCREASED
O2 NEEDS, 1L/NC BASELINE,
2L/NC HS, 3L/NC WITH
ACTIVITY.

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 (5)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID	USA-US070-2020-MRNA-1273-P30 1000019
Adverse event	CYTOKINE STORM
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	28 JAN 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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Number of Days in ICU	28
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

US3272026

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

ADMITTED FOR ARDS D/T
COVID-19 VIRUS. DIAGNOSED
WITH COVID PNEUMONIA IN
MID-NOVEMBER 2020 AND
SUBSEQUENTLY DEVELOPED
RESPIRATORY FAILURE D/T
ASSOCIATED ARDS AND
REQUIRED EMERGENT
INTUBATION AT THE END OF
THE MONTH DUE TO SEVERE
HYPOXIA. DESPITE MAXIMAL
VENT SETTINGS, THE PATIENT
COULD NOT MAINTAIN
ADEQUATE OXYGEN
SATURATION AND WAS SENT
TO A REGIONAL HOSPITAL AT
THE BEGINNING OF DECEMBER
FOR EVALUATION FOR VV
ECMO. PARTICIPANT WAS
CANNULATED AND
EVENTUALLY REQUIRED
TRACHEOSTOMY D/T
PRLONGED VENTILATION
REQUIREMENTS. ECMO WAS
DECANNULATED 01JAN2021.
HOSPITAL COURSE WAS
COMPLICATED BY VRE
BACTEREMIA, TRACH SITE
BLEEDING, EPISTAXIS AND
THROMBOCYTOPENIA WITH
BOTH HEME/ONC AND ID ON
BOARD. PARTICIPANT
SEROTONIN RELEASE ASSAY IS
NEGATIVE MAKING HIT LESS
LIKELY. PARTICIPANT

US3272026

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

COMPLETED ANTIBIOTICS AND
WAS STARTED ON
PREDNISONE WITH CONCERN
CAP. ON PREDNISONE TAPER
WITH BACTRIM ON BOARD.
DISMISSED TO LOCAL REHAB
FACILITY WHERE HE HAD
HEMORRHAGING FROM HIS
TRACHEA AND WAS
TRANSFERRED BACK FOR
EVALUATION. HEMORRHAGE
RESOLVED WITHOUT
INTERVENTION,
TRACHEOSTOMY
DECANNULATION 25JAN2021.
TUBE FEEDINGS STOPPED AS
PO RESUMED. TRANSFERRED
BACK TO REHAB.
SUPPLEMENTAL 1-3L/NC WITH
ACTIVITY, DISCHARGED HOME
11FEB2021.

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

US3272026

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID	USA-US070-2020-MRNA-1273-P30 1000019
Adverse event	TRACHEAL HEMORRHAGE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	20 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	21 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	20 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	28 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

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

US3272026

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

PARTICIPANT WAS AT A
LONG-TERM REHABILITATION
FACILITY ON 20JAN2021 WHEN
HE BEGAN BLEEDING HEAVILY
FROM HIS TRACHEOSTOMY
SITE. HE WAS FLOWN BACK TO
THE HOSPITAL WHERE
IMAGING AND
BRONCHOSCOPY WERE
NEGATIVE FOR FISTULA OR
OTHER CAUSE.
ANTICOAGULATION WAS HELD
AND HEMORRHAGING
RESOLVED. PARTICIPANT
REMAINED INPATIENT FOR
TRACHEOSTOMY
DECANNULATION 25JAN2021.
THEY CONTINUED HIS
FONDAPARINUX FOR FIFTY (50)
MORE DAYS AND WILL
FOLLOW UP WITH VASCULAR
SURGERY. HE WAS
DISCHARGED BACK TO THE
REHABILITATION FACILITY
28JAN2021.

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 (7)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID	
Adverse event	DELIRIUM
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID

Adverse event

CONSTIPATION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

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)

28 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID

Adverse event

DEEP VEIN THROMBOSIS, LEFT
COMMON FEMORAL/LEFT
ILIAC

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)

01 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID

Adverse event

GASTROESOPHAGEAL REFLUX
DISEASE

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)

10 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID

Adverse event

TACHYCARDIA

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)

01 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID	
Adverse event	ANXIETY
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Form: Adverse Events (12)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID	USA-US070-2020-MRNA-1273-P30 1000019
Adverse event	VANCOMYCIN RESISTANT ENTEROCOCCUS BACTEREMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	28 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PARTICIPANT CONTINUED COURSE OF TREATMENT. BLOOD CULTURES BECAME POSITIVE 01JAN2021. ANTIBIOTICS CHANGED TO CEFEPIME. F/U BLOOD CULTURES WERE NEGATIVE.

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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)	

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID

Adverse event

RIGHT-SIDED EPISTAXIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 DEC 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 (14)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

PARTICIPANT WAS STARTED
ON HEPARIN FOR INITIATION
OF ECMO 02DEC2020
RESULTING IN ON-GOING
RIGHT-SIDED EPISTAXIS.
THESE WERE TREATED WITH
OXYMETAZOLINE NASAL
SPRAY AND RHINO ROCKETS
ON 13DEC2020 AND 21DEC2020.
ANTICOAGULATION WAS
CHANGED FROM HEPARIN TO
ARGATROBAN WITH
RESOLUTION OF SYMPTOMS
ON 23DEC2020.

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

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID	USA-US070-2020-MRNA-1273-P30 1000019
Adverse event	PSEUDOMONAS AERUGINOSA, PNEUMONIA, BILATERAL, VENTILATOR-ASSOCIATED PNEUMONIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	04 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	23 DEC 2020
Admitted to ICU?	Yes <input checked="" type="radio"/>

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Form: Adverse Events (15)

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	No	<input type="radio"/>
	Unknown	<input type="radio"/>
Number of Days in ICU		60
Persistent or significant disability or incapacity		False
Congenital anomaly or birth defect		False
Other medically important event		False
Relationship to investigational product	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
Relationship to Study Procedure	Not Related	<input checked="" type="radio"/>
	Related	<input type="radio"/>
	Not Applicable	<input type="radio"/>
Action taken with investigational product	None	<input type="radio"/>
	Dose Delayed	<input type="radio"/>
	Investigational Product	<input type="radio"/>
	Withdrawn	<input type="radio"/>
	Not Applicable	<input checked="" type="radio"/>
Other action taken (check all that apply)		
None		False
Concomitant Medication		True
Concomitant Procedure		True
Outcome	Fatal	<input type="radio"/>
	Not Recovered/Not Resolved	<input type="radio"/>
	Recovered/Resolved	<input checked="" type="radio"/>
	Recovered/Resolved with Sequelae	<input type="radio"/>
	Recovering/Resolving	<input type="radio"/>
	Unknown	<input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
Narrative		

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

14DEC2020 BRONCHOSCOPY
CULTURE REVEALED
PSEUDOMONAS AERUGINOSA
PNEUMONIA, BILATERALLY.
PARTICIPANT WAS
VENTILATED. STARTED ON
LEVOFLOXACIN 750MG DAILY
24DEC2020 TO 05JAN2021. STILL
CULTURED FOR
PSEUDOMONAS, CHANGED TO
CEFTAZIDIME 2G Q8 FROM
05JAN2021 TO 15JAN2021.

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 (17)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID	
Adverse event	INSOMNIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID

Adverse event

HYPERTENSION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID	USA-US070-2020-MRNA-1273-P30 1000019
Adverse event	THROMBOCYTOPENIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	01 JAN 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

Number of Days in ICU	60
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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PLATELETS 142K TO 69K
09DEC2020. ON HEPARIN DRIP
SECONDARY TO ECMO.
HEME/ONC REFERRAL. HIT
ANTIBODIES POSITIVE WITH
MODERATE RISE TO 1.34.
SEROTONIN RELEASE ASSAY
STUDY RULED OUT TRUE HIT,
CONSIDER REACTION TO BE
POST-PUMP SYNDROME
INDUCED
THROMBOCYTOPENIA.
HEPARIN CHANGED TO
ARGATROBAN TO
FONDAPARINUX. HEME/ONC
CONSIDERED
THROMBOCYTOPENIA
RESOLVED 01JAN2021, SIGNED
OFF.

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 (20)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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AEID	USA-US070-2020-MRNA-1273-P30 1000019
Adverse event	ADULT RESPIRATORY DISTRESS SYNDROME
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	20 JAN 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Form: Adverse Events (20)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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Number of Days in ICU	60
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	INCREASED O2 NEEDS: BASELINE: 1L/NC HS: 2L/NC ACTIVITY: 3L/NC
Narrative	

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Form: Adverse Events (20)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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ADMITTED FOR ARDS D/T
COVID-19 VIRUS. DIAGNOSED
WITH COVID PNEUMONIA IN
MID-NOVEMBER 2020 AND
SUBSEQUENTLY DEVELOPED
RESPIRATORY FAILURE D/T
ASSOCIATED ARDS AND
REQUIRED EMERGENT
INTUBATION AT THE END OF
THE MONTH DUE TO SEVERE
HYPOXIA. DESPITE MAXIMAL
VENT SETTINGS, THE PATIENT
COULD NOT MAINTAIN
ADEQUATE OXYGEN
SATURATION AND WAS SENT
TO A REGIONAL HOSPITAL AT
THE BEGINNING OF DECEMBER
FOR EVALUATION FOR VV
ECMO. PARTICIPANT WAS
CANNULATED AND
EVENTUALLY REQUIRED
TRACHEOSTOMY D/T
PRLONGED VENTILATION
REQUIREMENTS. ECMO WAS
DECANNULATED 01JAN2021.
HOSPITAL COURSE WAS
COMPLICATED BY VRE
BACTEREMIA, TRACH SITE
BLEEDING, EPISTAXIS AND
THROMBOCYTOPENIA WITH
BOTH HEME/ONC AND ID ON
BOARD. PARTICIPANT
SEROTONIN RELEASE ASSAY IS
NEGATIVE MAKING HIT LESS
LIKELY. PARTICIPANT

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Folder: Adverse Events

Form: Adverse Events (20)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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COMPLETED ANTIBIOTICS AND
WAS STARTED ON
PREDNISONE WITH CONCERN
CAP. ON PREDNISONE TAPER
WITH BACTRIM ON BOARD.
DISMISSED TO LOCAL REHAB
FACILITY WHERE HE HAD
HEMORRHAGING FROM HIS
TRACHEA AND WAS
TRANSFERRED BACK FOR
EVALUATION. HEMORRHAGE
RESOLVED WITHOUT
INTERVENTION,
TRACHEOSTOMY
DECANNULATION 25JAN2021.
TUBE FEEDINGS STOPPED AS
PO RESUMED. DISCHARGED
HOME 12FEB2021. INCREASED
O2 NEEDS, 1L/NC BASELINE,
2L/NC HS, 3L/NC WITH
ACTIVITY.

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 (21)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID

Adverse event

ORAL ULCERATIONS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

02 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Form: Adverse Events (21)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	DEVELOPED ORAL ULCERATIONS SECONDARY TO PROLONGED INTUBATION.
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 (22)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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AEID

Adverse event

LEFT POSTERIOR SHOULDER,
NON-PRURITIC,
NON-URTICARIAL, CIRCULAR
RASH

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 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy)

24 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

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

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐

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Form: Adverse Events (22)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (23)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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AEID

Adverse event

STEROID-INDUCED
HYPERGLYCEMIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

28 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)

28 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (23)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Adverse Events

Form: Adverse Events (24)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID

Adverse event

PAIN, GENERALIZED

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

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)

11 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (24)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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

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Folder: Adverse Events

Form: Adverse Events (25)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID

Adverse event

HYPOKALEMIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Form: Adverse Events (25)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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

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Folder: Adverse Events

Form: Adverse Events (26)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID

Adverse event

EDEMA, BILATERAL LOWER
EXTREMITIES

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)

03 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (26)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Adverse Events

Form: Adverse Events (28)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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AEID

Adverse event

LEFT LOWER LEG
PARESTHESIA

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)

10 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (28)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID

Adverse event

ESSENTIAL TREMOR

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

28 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (29)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Adverse Events

Form: Adverse Events (30)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID

Adverse event

PARESTHESIA OF SKIN, RIGHT
HAND, THIRD, FOURTH, FIFTH
FINGER

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)

10 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (30)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Adverse Events

Form: Adverse Events (31)

Data signed: (b) (4) 29 Apr 2021 16:56:04

Generated On: 09 Jun 2021 16:18:59

AEID

Adverse event

PRESSURE SORES, NOSE,
BILATERAL CHEEKS, COCCYX

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)

01 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (31)

Data signed: (b) (4) 29 Apr 2021 16:56:04

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

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Apr 2021 16:56:13

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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) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication FEXOFENADINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 (1)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication ALBUTEROL SULFATE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 90

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

If dose unit is Other, specify MCGS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication MULTIFOCAL PNEUMONIA

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 (3)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication ACUTE RESPIRATORY FAILURE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication PIPERACILLIN-TAZOBACTAM

Prophylaxis Yes ☐
No ☒

Indication MULTIFOCAL PNEUMONIA

Dose per administration 3/375

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication MULTIFOCAL PNEUMONIA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication MULTIFOCAL PNEUMONIA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication ENOXAPARIN

Prophylaxis Yes ☒
No ☐

Indication DVT PROPHYLAXIS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication REMDESIVIR

Prophylaxis Yes ☐
No ☒

Indication COVID 19

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	21 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication IPRATROPIUM-ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication COVID-19, ACUTE
RESPIRATORY FAILURE WITH
HYPOXIA, ARDS, ACUTE
ENCEPHALOPATHY

Dose per administration 0.5-2.5/3

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication ACUTE HYPOXIC RESPIRATORY
FAILURE SECONDARY TO ARDS
FROM COVID 19

Dose per administration 60

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) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 1.0

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication 0.9 SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication ACUTE KIDNEY INJURY

Dose per administration 65

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

PER HOUR

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) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication DEXTROMETHORPHAN-GUAIFE
NESIN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication FLUITCASONE PROPIONATE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication RE- RUXOLITINIB (JAKAFI)
TABLET

Prophylaxis Yes ☐
No ☒

Indication COVID 19

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 (16)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication SUPERIMPOSED BACTERIAL
INFECTION SECONDARY TO
COVID-19 ILLNESS

Dose per administration 1750

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication MEROPENEM

Prophylaxis Yes ☐
No ☒

Indication SUPERIMPOSED BACTERIAL
INFECTION SECONDARY TO
COVID-19

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 (18)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	03 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication THIAMINE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication VITAMIN C

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication ZINC SULFATE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 220

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication DEXMEDETOMIDINE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 0.3

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

If dose unit is Other, specify MCG/KG

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 PER HOUR

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication MORPHINE SULFATE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication CISATRACURIUM (NIMBEX)
INFUSION

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 3

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

If dose unit is Other, specify MCG/KG/MIN

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 (25)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication EPOPROSTENOL

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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

HOURLY

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 162

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

If dose unit is Other, specify MCG/HOUR

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) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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 (28)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input checked="" type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication DIPRIVAN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 40

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

If dose unit is Other, specify MCG/KG

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 MINUTE

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication GUAIFENISEN

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 600

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) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication BENZONATATE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication CONVALESCENT PLASMA

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication PETROLATUM MINERAL OIL

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 1

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

If dose unit is Other, specify LINE/EYE

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		EXTERNAL EYES
Start date (dd MMM yyyy)		28 NOV 2020
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication NOREPINEPHRINE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 0.05

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

If dose unit is Other, specify MCG/KG

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 MINUTE

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication MIDAZOLAM

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 2-4

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

HOURLY

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) 29 Apr 2021 16:56:07

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	30 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication PROMETHAZINE-CODEINE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 6.25-10

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 (39)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication CHLORHEXIDINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR
PREVENTION OF ORAL
CANDIDIASIS

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	SWISH AND SPIT	
Start date (dd MMM yyyy)	01 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	28 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication DVT PROPHYLAXIS
SECONDARY TO
HOSPITALIZATION
SECONDARY TO COVID-19

Dose per administration 5000

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

If dose unit is Other, specify UNITS

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 (41)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication NICARDIPINE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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 INFUSION

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication METOPROLOL TARTRATE

Prophylaxis Yes ☐
No ☒

Indication TACHYCARDIA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 20 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE WITHOUT
ESOPHAGITIS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication PNEUMOVAX

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		28 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication INFLUENZA QUAD-QIV

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		28 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication CEFEPIME

Prophylaxis Yes ☐
No ☒

Indication MULTIFOCAL PNEUMONIA

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 (48)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	22 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication BACITRACIN

Prophylaxis Yes ☐
No ☒

Indication LEFT POSTERIOR SHOULDER,
NON-PRURITIC, CIRCULAR
RASH

Dose per administration 1

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

If dose unit is Other, specify APPLICATION- 500 UNIT/GRAM
OINTMENT

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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Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	09 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication HYDROMORPHONE 50 MG IN
DEXTROSE 5% 100ML

Prophylaxis Yes ☐
No ☒

Indication EXTRACORPOREAL
MEMBRANE OXYGENATION
SECONDARY TO ADULT
RESPIRATORY DISTRESS
SYNDROME

Dose per administration 0-8

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

CONTINUOUS

Route of administration Oral ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

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	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

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Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication MULTIFOCAL PNEUMONIA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		15 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

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Name of Medication ARGATROBAN

Prophylaxis Yes ☐
No ☒

Indication EXTRACORPOREAL
MEMBRANOUS OXYGENATION

Dose per administration 0-10

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

If dose unit is Other, specify MCG/KG/MIN

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

If frequency is Other, specify CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication DELIRIUM, INSOMNIA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication EXTRACORPOREAL
MEMBRANOUS OXYGENATION

Dose per administration 50

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

If dose unit is Other, specify MCG/HR

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

If frequency is Other, specify EVERY 72 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	05 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

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Name of Medication INSULIN GLARGINE

Prophylaxis Yes ☐
No ☒

Indication STEROID-INDUCED
HYPERGLYCEMIA

Dose per administration 10

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

If dose unit is Other, specify UNITS

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 (55)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Form: Prior/Concomitant Medication and Vaccination (56)

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Name of Medication INSULIN LISPRO

Prophylaxis Yes ☐
No ☒

Indication STEROID-INDUCED
HYPERGLYCEMIA

Dose per administration 1-7

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

If dose unit is Other, specify UNITS

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)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

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Name of Medication INFLUENZA QUAD-QIV

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

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	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		28 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

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Name of Medication DOCUSATE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication ESCITALOPRAM OXALATE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Form: Prior/Concomitant Medication and Vaccination (59)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Form: Prior/Concomitant Medication and Vaccination (60)

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Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Form: Prior/Concomitant Medication and Vaccination (60)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication FONDAPARINUX

Prophylaxis Yes ☐
No ☒

Indication LEFT LOWER LEG DEEP VEIN
THROMBOSIS

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 (61)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication FONDAPARINUX

Prophylaxis Yes ☐
No ☒

Indication LEFT LOWER LEG, DEEP VEIN
THROMBOSIS

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication MICONAZOLE 2%

Prophylaxis Yes ☐
No ☒

Indication LEFT POSTERIOR SHOULDER
NON-PRURITIC,
NON-URTICARIAL, CIRCULAR
RASH

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	05 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication LACTOBACILLUS RHAMNOSUS

Prophylaxis Yes ☐
No ☒

Indication MULTIFOCAL PNEUMONIA

Dose per administration 10

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

If dose unit is Other, specify BILLION CELL CAPSULE

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication POLYETHYLENE GLYCOL

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

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Generated On: 09 Jun 2021 16:18:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication TRIMETHOPRIM-SULFAMETHO
XAZOLE

Prophylaxis Yes ☒
No ☐

Indication PNEUMONIA PROPHYLAXIS
SECONDARY TO STEROIDS

Dose per administration 800-160

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

If dose unit is Other, specify

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

If frequency is Other, specify

THREE TIMES/WEEK

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication QUETIAPINE

Prophylaxis Yes ☐
No ☒

Indication DELIRIUM

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication ADULT RESPIRATORY
DISTRESS SYNDROME

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 (68)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication ADULT RESPIRATORY
DISTRESS SYNDROME

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	17 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication ADULT RESPIRATORY
DISTRESS SYNDROME

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication ADULT RESPIRATORY
DISTRESS SYNDROME

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication IPRATROPIUM-ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication COVID-19, ADULT
RESPIRATORY DISTRESS
SYNDROME

Dose per administration 0.5-2.5/3

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication AMOXICILLIN

Prophylaxis Yes ☒
No ☐

Indication RHINO ROCKET PACKING
PROPHYLAXIS

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication QUETIAPINE

Prophylaxis Yes ☐
No ☒

Indication DELIRIUM

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 (74)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication LEFT LOWER LEG DEEP VEIN
THROMBOSIS,
EXTRACORPOREAL
MEMBRANE OXYGENATION

Dose per administration 81

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 (75)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication TOBRAMYCIN

Prophylaxis Yes ☐
No ☒

Indication ADULT RESPIRATORY
DISTRESS SYNDROME,
VANCOMYCIN-RESISTANT
ENTEROCOCCUS SEPTICEMIA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication SECONDARY TO DIURETIC
USAGE SECONDARY TO
EXTRACORPOREAL
MEMBRANOUS OXYGENATION
SECONDARY TO ADULT
RESPIRATORY DISTRESS
SYNDROME

Dose per administration 40

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

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	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	05 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication ADULT RESPIRATORY
DISTRESS SYNDROME

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 (78)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	11 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication SCOPOLAMINE PATCH

Prophylaxis Yes ☒
No ☐

Indication POSTOPERATIVE
NAUSEA/VOMITING

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

ONCE PER 72 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication MULTIFOCAL PNEUMONIA,
ADULT RESPIRATORY
DISTRESS SYNDROME

Dose per administration 125

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 (82)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	03 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication PAIN, GENERALIZED

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Form: Prior/Concomitant Medication and Vaccination (83)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication BISACODYL

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input checked="" type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication ACETAZOLAMIDE

Prophylaxis Yes ☐
No ☒

Indication EXTRACORPOREAL
MEMBRANE OXYGENATION
SECONDARY TO ADULT
RESPIRATORY DISTRESS
SYNDROME

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	12 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication FENTANYL PATCH

Prophylaxis Yes ☐
No ☒

Indication PAIN, GENERALIZED

Dose per administration 75

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

If dose unit is Other, specify MCG

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 Q72 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA, DELIRIUM

Dose per administration 9

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 (87)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication KETAMINE

Prophylaxis Yes ☐
No ☒

Indication EXTRACORPOREAL
MEMBRANE OXYGENATION
SECONDARY TO ADULT
RESPIRATORY SYNDROME,
DELIRIUM SECONDARY TO
SEDATION SECONDARY TO
ADULT RESPIRATORY
SYNDROME

Dose per administration 0.05-1.00

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

If dose unit is Other, specify MG/KG

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 /HOUR

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Route of administration	Oral	<input type="checkbox"/>
	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication IPRATROPIUM-ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ADULT RESPIRATORY
DISTRESS SYNDROME

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 Q4HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication BIOTENE
(SODIUM
MONOFLUOROPHOSPHATE)

Prophylaxis Yes ☐
No ☒

Indication ORAL ULCERATIONS

Dose per administration 0.125-0.25

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 (90)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication EXTRACORPOREAL
MEMBRANE OXYGENATION
SECONDARY TO ADULT
RESPIRATORY DISTRESS
SYNDROME

Dose per administration 30

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 JAN 2021
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 JAN 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication LINEZOLID

Prophylaxis Yes ☐
No ☒

Indication VANCOMYCIN-RESISTANT
ENTEROCOCCUS SEPTICEMIA,
VENTILATOR ASSOCIATED
PNEUMONIA, PSEUDOMONAS
BILATERAL

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify _____		
<hr/>		
Start date (dd MMM yyyy)		02 JAN 2021
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		02 JAN 2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication MERREM

Prophylaxis Yes ☐
No ☒

Indication ADULT RESPIRATORY
DISTRESS SYNDROME

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 (93)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	03 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication EXTRACORPOREAL
MEMBRANE OXYGENATION
SECONDARY TO ADULT
RESPIRATORY DISTRESS
SYNDROME

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐

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Form: Prior/Concomitant Medication and Vaccination (94)

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	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	01 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

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Form: Prior/Concomitant Medication and Vaccination (95)

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Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication PAIN, GENERALIZED

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q4HOURS

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

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Name of Medication FENTANYL PATCH

Prophylaxis Yes ☐
No ☒

Indication PAIN, GENERALIZED

Dose per administration 100

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

If dose unit is Other, specify MCG/HR/PATCH

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

If frequency is Other, specify Q72HOURS

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

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Name of Medication ALBUMIN HUMAN 25%

Prophylaxis Yes ☐
No ☒

Indication ALTERED FLUID STATUS
SECONDARY TO
EXTRACORPOREAL
MEMBRANE OXYGENATION
SECONDARY TO ADULT
RESPIRATORY DISTRESS
SYNDROME

Dose per administration 25/100

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

If dose unit is Other, specify G/ML

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

If frequency is Other, specify

Route of administration Oral ☐

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	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication PAIN, GENERALIZED

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 10 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Name of Medication SILVER NITRATE

Prophylaxis Yes ☐
No ☒

Indication RIGHT-SIDED EPISTAXIS

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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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication VENTILATOR-ASSOCIATED
PNEUMONIA, PSEUDOMONAS
BILATERAL

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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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	08 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication VENTILATOR-ASSOCIATED
PNEUMONIA, PSEUDOMONAS
BILATERAL

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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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	18 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	22 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Name of Medication DELTASONE

Prophylaxis Yes ☐
No ☒

Indication ACUTE RESPIRATORY FAILURE

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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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Name of Medication ALBUTEROL SULFATE

Prophylaxis Yes ☐
No ☒

Indication COVID-19

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Name of Medication OXYMETAZOLINE
0.025%/LIDOCAINE 2%

Prophylaxis Yes ☐
No ☒

Indication RIGHT-SIDED EPISTAXIS

Dose per administration 1-2

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

If dose unit is Other, specify SPRAYS/NARE

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 (105)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input checked="" type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication ADULT RESPIRATORY
DISTRESS SYNDROME

Dose per administration 60

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 (106)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	31 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	01 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication METHYLPREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication ADULT RESPIRATORY
DISTRESS SYNDROME

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		02 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication INSULIN LISPRO

Prophylaxis Yes ☐
No ☒

Indication STEROID-INDUCED
HYPERGLYCEMIA

Dose per administration 3-21

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

If dose unit is Other, specify UNITS

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 (109)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	02 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication TACHYCARDIA

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 (110)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication METOPROLOL TARTRATE

Prophylaxis Yes ☐
No ☒

Indication TACHYCARDIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication MORPHINE SULFATE

Prophylaxis Yes ☐
No ☒

Indication PAIN, GENERALIZED

Dose per administration 2-4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		28 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication PAIN, GENERALIZED

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication QUETIAPINE

Prophylaxis Yes ☐
No ☒

Indication DELIRIUM/INSOMNIA

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication DOCUSATE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 50/5

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication ADULT RESPIRATORY
DISTRESS SYNDROME

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 (117)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication ADULT RESPIRATORY
DISTRESS SYNDROME

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	17 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication ADULT RESPIRATORY
DISTRESS SYNDROME

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication ADULT RESPIRATORY
DISTRESS SYNDROME

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	31 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	07 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication ESMOLOL

Prophylaxis Yes ☐
No ☒

Indication EXTRACORPOREAL
MEMBRANE OXYGENATION
SECONDARY TO ADULT
RESPIRATORY DISTRESS
SYNDROME

Dose per administration 50/200

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

If dose unit is Other, specify MCG/KG/MIN

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

If frequency is Other, specify CONTINUOUS

Route of administration Oral ☐
Topical ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

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	Subcutaneous	<input type="radio"/>
	Transdermal	<input type="radio"/>
	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	07 DEC 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication EXTRACORPOREAL
MEMBRANE OXYGENATION
SECONDARY TO ADULT
RESPIRATORY DISTRESS
SYNDROME, COVID-19

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication ACETAZOLAMIDE

Prophylaxis Yes ☐
No ☒

Indication EXTRACORPOREAL
MEMBRANE OXYGENATION
SECONDARY TO ADULT
RESPIRATORY DISTRESS
SYNDROME

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

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	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 23 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication CEFAZOLIN

Prophylaxis Yes ☒
No ☐

Indication BRONCHOSCOPY
PROPHYLAXIS

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 (124)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication INFLUENZA QUAD-QIV

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		28 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication MULTIFOCAL PNEUMONIA

Dose per administration 1750

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 (126)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 DEC 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 14 DEC 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

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Form: Prior/Concomitant Medication and Vaccination (127)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication AMPICILLIN/SULBACTAM

Prophylaxis Yes ☒
No ☐

Indication EXTRACORPOREAL
MEMBRANE OXYGENATION
CIRCUIT EXCHANGE
PROPHYLAXIS

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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Form: Prior/Concomitant Medication and Vaccination (127)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

	Transdermal	<input type="radio"/>
	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	29 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication ALOE VESTA PROTECTANT
OINTMENT #3

Prophylaxis Yes ☐
No ☒

Indication PRESSURE SORES, NOSE,
BILATERAL CHEEKS, COCCYX

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication CEFEPIME

Prophylaxis Yes ☐
No ☒

Indication MULTIFOCAL PNEUMONIA

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication LEFT LOWER EXTREMITY
PARESTHESIA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication LEFT LOWER LEG
PARASTHESIA

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	05 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Data signed: (b) (4) 29 Apr 2021 16:56:07

Generated On: 09 Jun 2021 16:18:59

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPOKALEMIA

Dose per administration 20

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

If dose unit is Other, specify 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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	09 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication EDEMA, BILATERAL LOWER
EXTREMITIES

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	08 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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Name of Medication COVID VACCINE (PFIZER)

Prophylaxis Yes ☒
No ☐

Indication COVID PREVENTION

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Data signed: (b) (4) 29 Apr 2021 16:56:07

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	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2021
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Apr 2021 16:56:13

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Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Apr 2021 16:56:13

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Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
17 NOV 2020	MIDLINE PLACEMENT, SINGLE LUMEN	Adverse Event	
28 NOV 2020	ARTERIAL LINE, RIGHT ARM	Adverse Event	
28 NOV 2020	OROGASTRIC TUBE INSERTION	Adverse Event	
28 NOV 2020	FOLEY CATHETER PLACED	Adverse Event	
28 NOV 2020	INTUBATED	Adverse Event	
02 DEC 2020	FEMORAL-FEMORAL VENO-VENOUS EXTRACORPOREAL MEMBRANE MACHINE CATHETERIZATION.	Adverse Event	
16 NOV 2020	BIPAP INITIATED	Adverse Event	
18 JAN 2021	BRONCHOSCOPY	Adverse Event	
10 DEC 2020	TRACHEOTOMY/TRACHEOSTOMY	Adverse Event	
25 JAN 2021	TRACHEA DECANNULATION	Adverse Event	
06 JAN 2021	INFERIOR VENA CAVA FILTER PLACEMENT	Adverse Event	
14 DEC 2020	BRONCHOSCOPY	Adverse Event	
21 DEC 2020	RHINO ROCKET PROCEDURE	Adverse Event	
23 DEC 2020	BRONCHOSCOPY	Adverse Event	
31 DEC 2020	BRONCHOSCOPY	Adverse Event	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Data signed: (b) (4) 29 Apr 2021 16:56:13

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
14 DEC 2020	EXTRACORPOREAL MEMBRANE OXYGENATION CIRCUIT EXCHANGE	Adverse Event	
17 DEC 2020	EXTRACORPOREAL MEMBRANE OXYGENATION CIRCUIT EXCHANGE	Adverse Event	
26 DEC 2020	EXTRACORPOREAL MEMBRANE OXYGENATION CIRCUIT EXCHANGE	Adverse Event	
01 JAN 2021	FEMORAL-FEMORAL VEN-VEIN EXTRACORPOREAL MEMBRANE MACHINE DE-CANNULATION	Adverse Event	
04 DEC 2020	BRONCHOSCOPY	Adverse Event	
08 DEC 2020	BRONCHOSCOPY	Adverse Event	
13 DEC 2020	BRONCHOSCOPY	Adverse Event	
28 NOV 2020	TUBE FEEDING	Adverse Event	
14 DEC 2020	ENEMA, SMOG	Adverse Event	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

Date of study discontinuation/completion (dd MMM yyyy) 25 MAR 2021

Reason for discontinuation

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

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

SUBJECT RECEIVED NON-STUDY VACCINE OUTSIDE OF STUDY. PER SPONSOR SUBJECT IS TO BE DISCONTINUED.

If reason for discontinuation is Death, main cause of death

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

If main cause of death is Other, specify

Date of death (dd MMM yyyy) _____

Was autopsy performed?

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

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Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	17/NOV/2020 14:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	18/NOV/2020 10:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	20/NOV/2020 15:02
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

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	30/NOV/2020 17:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (5)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	06/DEC/2020 15:55
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

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (6)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	False

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (7)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	11/DEC/2020 09:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (8)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	11/DEC/2020 20:25
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

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (9)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	15/DEC/2020 09:20
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

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (10)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	16/DEC/2020 09:09
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

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (11)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	False

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (12)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	21/DEC/2020 11:49
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

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (13)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	22/DEC/2020 21:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (14)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	29/JAN/2021 13:49
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

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (15)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	05/FEB/2021 14:22
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

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (16)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	08/FEB/2021 12:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (17)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	False

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (18)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	16/FEB/2021 12:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (19)

Data signed: (b) (4) 29 Apr 2021 16:56:16

Generated On: 09 Jun 2021 16:18:59

SAEID	USA-US070-2020-MRNA-1273-P301000019
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input checked="" type="radio"/> No <input type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	ADAM
Investigator's Last Name	BROSZ
Site Address: Street	2444 W. FAIDLEY AVE
Site Address: City	GRAND ISLAND
Site Address: State	NE
Site Address: Postal Code	68803
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	16
Date of submission (Pre-filled from custom function)	18/FEB/2021 09:34
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

Audit

US3272026 (Prod: Meridian Clinical Research (Grand Island, Nebraska))

US3272026

Form: Participant Creation

Generated On: 09 Jun 2021 16:18:59

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:55:17
User entered 'US3272026'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 14:39:10

US3272026

Form: Participant Creation

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:19
User entered 'Yes (Y)'	Kayla Flege (b) (4)	01 Aug 2020 15:16:46
	(b) (4)	

US3272026

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:11:41
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	10 Sep 2020 15:45:09
User entered '01 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 15:45:09
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	09 Sep 2020 22:16:09
User entered '28 Jul 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:16:09
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	09 Sep 2020 22:15:11
User entered '01 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:15:11
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	09 Sep 2020 22:14:38
User closed query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	09 Sep 2020 22:14:38
Query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	09 Sep 2020 22:14:38
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	09 Sep 2020 22:14:38
User entered '28 Jul 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 22:14:38
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	09 Sep 2020 22:14:03
User opened query 'Screening Visit Date is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	09 Sep 2020 22:14:03

US3272026

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 22:14:03
User entered '30 Jun 2020' reason for change: Data Entry Error		09 Sep 2020 22:14:03
DataPoint Verified.		21 Aug 2020 17:51:19
User entered '01 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 14:39:11

US3272026

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:19
User entered 'Clinic (Clinic)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:16:46

US3272026

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered 'SCRN'	System	01 Aug 2020 15:16:46

US3272026

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:59

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '(b) (6) 1974'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 14:39:12

US3272026

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:59

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '46'	Kayla Flege (b) (4)	01 Aug 2020 15:17:10
	(b) (4)	

US3272026

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:59

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered 'YEARS'	System	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered '46'	System	01 Aug 2020 15:17:22

US3272026

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:59

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered 'Male (M)'	Kayla Flege (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:59

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered 'I'	Kayla Flege (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:59

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '0'	Kayla Flege (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:59

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '0'	Kayla Flege (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '0'	Kayla Flege (b) (4)	01 Aug 2020 15:17:10
	(b) (4)	

US3272026

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '0'	Kayla Flege (b) (4)	01 Aug 2020 15:17:10
	(b) (4)	

US3272026

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '0'	Kayla Flege (b) (4)	01 Aug 2020 15:17:10

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Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:59

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered empty.	Kayla Flege (b) (4)	01 Aug 2020 15:17:10
	(b) (4)	

US3272026

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:59

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '0'	Kayla Flege (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:18:59

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:36
User entered '0'	Kayla Flege (b) (4)	01 Aug 2020 15:17:10

US3272026

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:59

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:11:57
User entered '01 Aug 2020'	Kayla Flege (b) (4)	01 Aug 2020 15:17:22
	(b) (4)	

US3272026

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered 'Aug 2020'	System	01 Aug 2020 15:17:22

US3272026

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered '2020'	System	01 Aug 2020 15:17:22

US3272026

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:59

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:11:57
User entered 'Amendment 1 (1)'	Kayla Flege (b) (4)	01 Aug 2020 15:17:22

US3272026

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:11:57
User entered 'Yes (Y)'	Kayla Flege (b) (4)	01 Aug 2020 15:17:22
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:11:57
User entered empty.	Kayla Flege (b) (4)	01 Aug 2020 15:17:22
	(b) (4)	

US3272026

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:59

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:11:57
User entered empty.	Kayla Flege (b) (4)	01 Aug 2020 15:17:22
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:11:57
User entered 'No (N)'	Kayla Flege (b) (4)	01 Aug 2020 15:17:22

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:11:57
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 14:39:11

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:18:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered 'I'	System	01 Aug 2020 15:17:27

US3272026

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:43
User entered 'Yes (Y)'	Kayla Flege (b) (4)	01 Aug 2020 15:17:27
	(b) (4)	

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Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:18:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:45
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:20:10

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
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)	01 Aug 2020 16:22:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 16:22:04
Data point term sent to Coder	System	01 Aug 2020 16:21:31
User entered 'seasonal allergies'	Ashley Bell (b) (4)	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User entered 'un UNK 2013'	Ashley Bell (b) (4)	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered 'Jan 2013'	System	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered '2013'	System	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered empty.	System	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered empty.	System	01 Aug 2020 16:20:35

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 16:22:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 16:22:04
Data point term sent to Coder	System	01 Aug 2020 16:21:33
User entered 'Vasectomy'	Ashley Bell (b) (4)	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User entered 'un UNK 2002'	Ashley Bell (b) (4)	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:21:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Aug 2020 16:21:08
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:21:08
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:21:02
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:21:02

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User entered 'un UNK 2002'	Ashley Bell (b) (4)	01 Aug 2020 16:21:02

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered 'Jan 2002'	System	01 Aug 2020 16:21:02

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered '2002'	System	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered 'Jan 2002'	System	01 Aug 2020 16:21:02

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered '2002'	System	01 Aug 2020 16:21:02

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Cutaneous neoplasms benign, HLT: Skin neoplasms benign, PT: Acrochordon, LLT: Skin tags - version MedDRA\\23.0.	Coder Import (b) (4)	02 Aug 2020 13:48:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Aug 2020 13:48:16
Data point term sent to Coder	System	01 Aug 2020 16:22:34
User entered 'Bilateral Axillary Skin Tags'	Ashley Bell (b) (4)	01 Aug 2020 16:22:23

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User entered 'un UNK 2010'	Ashley Bell (b) (4)	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:23:13
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered 'Jan 2010'	System	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered '2010'	System	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered empty.	System	01 Aug 2020 16:22:23

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered empty.	System	01 Aug 2020 16:22:23

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:12:36
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" . Please provide missing data below and review/update response to 'Were vital signs assessed? as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:45:06
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" . Please provide missing data below and review/update response to 'Were vital signs assessed? as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:11:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" . Please provide missing data below and review/update response to 'Were vital signs assessed? as per CCGs.' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:46:09
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:46:09
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' answered with 'vitals in visit 1 day 1 as screening was done same day' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 20:42:36
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCGs pages 15-16, data to be entered for date, time, height and weight. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:54:35
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
DataPoint Verified.		21 Aug 2020 17:51:49
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:12:36
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Date of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:45:08
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Date of assessment is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:11:11
User entered '01 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Date of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:46:27
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 15:45:09
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	10 Sep 2020 15:45:09
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 15:44:57
User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	10 Sep 2020 15:44:57
User entered '01 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 15:44:57
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 22:17:01
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	09 Sep 2020 22:17:01

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System). DataPoint Un-verified.	System	09 Sep 2020 22:17:01
	(b) (4), (b) (6)	09 Sep 2020 22:17:01
User entered '28 Jul 2020' reason for change: Data Entry Error		09 Sep 2020 22:17:01
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 22:16:09
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 22:15:11
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	09 Sep 2020 22:15:11
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 22:14:03
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 16:29:45
User entered '01 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:29:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 16:29:36
User entered '01 Dec ' (non-conformant).	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:12:36
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Time of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:45:10
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Time of assessment is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:11:15
User entered '08:47' reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Time of assessment is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:46:41
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User entered '08:47'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered '01 Aug 2020 08:47'	System	30 Sep 2020 18:11:02
User entered empty.	System	15 Sep 2020 23:24:15
User entered '01 Aug 2020 08:47'	System	10 Sep 2020 15:44:57
User entered '28 Jul 2020 08:47'	System	09 Sep 2020 22:17:01
User entered '01 Aug 2020 08:47'	System	01 Aug 2020 16:29:45
User entered '01 Dec 08:47' (non-conformant).	System	01 Aug 2020 16:29:36

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Folder: Screening

Form: Vital Signs

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Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:12:36
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Height is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:45:12
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Height is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:11:18
User entered '185.0' cm reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Height is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:46:59
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 16:32:50
User entered '185.0' cm reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:32:50
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 16:30:46
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Aug 2020 16:30:46
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	01 Aug 2020 16:30:46
User entered '185' (non-conformant).	Ashley Bell (b) (4)	01 Aug 2020 16:30:46
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Aug 2020 16:29:36
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:29:36
DataPoint set to visible.	System	01 Aug 2020 15:17:27

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:12:36
User closed query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Weight is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:45:14
Query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Weight is missing. Please provide as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:11:22
User entered '123.2' kg reason for change: Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
User opened query 'Per CDM: Patient Screened/Dosed (V1D1) same day "01AUG2020" .Weight is missing. Please provide as per CCGs.' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:47:14
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User entered '123.2' kg	Ashley Bell (b) (4)	01 Aug 2020 16:29:36
DataPoint set to visible.	System	01 Aug 2020 15:17:27

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered '35.99708'	System	30 Sep 2020 18:11:02
User entered empty.	System	15 Sep 2020 23:24:15
User entered '36.0'	System	01 Aug 2020 16:32:50
User entered empty.	System	01 Aug 2020 16:29:36
DataPoint set to visible.	System	01 Aug 2020 15:17:27

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered 'kg/m2'	System	30 Sep 2020 18:11:02
User entered empty.	System	15 Sep 2020 23:24:15
User entered 'kg/m2'	System	01 Aug 2020 16:32:50
User entered empty.	System	01 Aug 2020 16:29:36
DataPoint set to visible.	System	01 Aug 2020 15:17:27

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:12:36
User closed query 'Per CDM: Thanks for your response however, If Screening and dosing (V1D1) are done on the same day (01AUG2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done "to avoid duplication. Please update these fields as per CCGs.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:45:17
Query 'Per CDM: Thanks for your response however, If Screening and dosing (V1D1) are done on the same day (01AUG2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done "to avoid duplication. Please update these fields as per CCGs.' answered with 'updated ' (Site from DM).	Ashley Bell (b) (4)	30 Sep 2020 18:11:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
User opened query 'Per CDM: Thanks for your response however, If Screening and dosing (V1D1) are done on the same day (01AUG2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done "to avoid duplication. Please update these fields as per CCGs.' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:47:32
User closed query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 15:47:32
Query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 23:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15

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Folder: Screening

Form: Vital Signs

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Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User opened query 'Per CDM:Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 20:25:07
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:49
User entered '36.7' C	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:12:36
DataPoint Un-verified.		15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:24:15
DataPoint Verified.		21 Aug 2020 17:51:49
User entered 'Other (Other)'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:12:36
DataPoint Un-verified.		15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:24:15
DataPoint Verified.		21 Aug 2020 17:51:49
User entered 'tympanic'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:12:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:24:15
DataPoint Verified.		21 Aug 2020 17:51:49
User entered '78'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered 'bpm'	System	30 Sep 2020 18:11:02
User entered empty.	System	15 Sep 2020 23:24:15
User entered 'bpm'	System	01 Aug 2020 16:29:36

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Folder: Screening

Form: Vital Signs

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:12:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:24:15
DataPoint Verified.		21 Aug 2020 17:51:49
User entered '24'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

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Folder: Screening

Form: Vital Signs

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered 'breaths/min'	System	30 Sep 2020 18:11:02
User entered empty.	System	15 Sep 2020 23:24:15
User entered 'breaths/min'	System	01 Aug 2020 16:29:36

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:12:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:24:15
DataPoint Verified.		21 Aug 2020 17:51:49
User entered '144' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:33:22
User entered '143'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered 'mmHg'	System	30 Sep 2020 18:11:02
User entered empty.	System	15 Sep 2020 23:24:15
User entered 'mmHg'	System	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:12:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	30 Sep 2020 18:11:02
DataPoint Un-verified.	(b) (4), (b) (6)	15 Sep 2020 23:24:15
User entered empty; reason for change Data Entry Error		15 Sep 2020 23:24:15
DataPoint Verified.		21 Aug 2020 17:51:49
User closed query 'Re-Query : Please confirm if this can be reported as an AE. If so, please report on the AE form, else clarify. Thank you.' (Site from DM).		19 Aug 2020 06:28:39
Query 'Re-Query : Please confirm if this can be reported as an AE. If so, please report on the AE form, else clarify. Thank you.' answered with 'NO AE' (Site from DM).	Ashley Bell (b) (4)	15 Aug 2020 13:56:29
User opened query 'Re-Query : Please confirm if this can be reported as an AE. If so, please report on the AE form, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Aug 2020 14:54:17
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 14:40:34
User entered '90' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:33:22
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Ashley Bell (b) (4)	01 Aug 2020 16:32:03
User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		01 Aug 2020 16:29:36
User entered '103'	Ashley Bell (b) (4)	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User entered 'mmHg'	System	30 Sep 2020 18:11:02
User entered empty.	System	15 Sep 2020 23:24:15
User entered 'mmHg'	System	01 Aug 2020 16:29:36

US3272026

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09

US3272026

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:12:42
DataPoint Un-verified.		11 Sep 2020 14:06:49
User entered 'No (N)' reason for change: Data Entry Error		11 Sep 2020 14:06:49
DataPoint Verified.		21 Aug 2020 17:51:59
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:33:35

US3272026

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:12:42
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 14:06:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 14:06:49
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 16:19:02
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	09 Sep 2020 16:19:02
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	09 Sep 2020 16:19:02
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 16:19:02
User entered '01 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 16:19:02
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 16:18:55
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	09 Sep 2020 16:18:55
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 16:18:55
DataPoint Un-verified.	(b) (4), (b) (6)	09 Sep 2020 16:18:55
User entered '02 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 16:18:55
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 23:11:27

US3272026

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:51:59
User entered '01 Aug 2020'	Ashley Bell (b) (4)	01 Aug 2020 16:33:35

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

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)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

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)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

[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)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

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)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

[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)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

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)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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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)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

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)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

[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)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

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)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered 'I'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:18:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:53:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:05
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:34:05

US3272026

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:53
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:21

US3272026

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:53
User entered '01 Aug 2020'	Ashley Bell (b) (4)	01 Aug 2020 16:34:21

US3272026

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:53
User entered 'Clinic (Clinic)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:21

US3272026

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered 'VISIT1'	System	01 Aug 2020 16:34:21

US3272026

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:59
User entered '01 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 14:44:13

US3272026

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:18:59

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:59
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:36:27
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:36:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 14:44:13
User entered '100363' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 14:44:13

US3272026

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:59
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Aug 2020 14:44:13

US3272026

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:18:59

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)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:59
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:36

US3272026

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:18:59

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)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:59
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:36

US3272026

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:59
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:36

US3272026

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:59
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:36

US3272026

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:18:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:59
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:34:36

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User closed query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:17:28
Query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' answered with 'confirm correct' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:01:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:01:44
User opened query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:04
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:04
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:44:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:44:11
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:25:57
User entered '185.0' cm	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:01:44
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:19
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:44:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:44:11
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:26:07
User entered '123.2' kg	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User closed query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:17:28
Query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' answered with 'confirm correct' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:01:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:01:44
User opened query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:04
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:04
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:44:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:44:11
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:25:57
User entered '185.0' cm	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:01:44
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:19
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:44:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:44:11
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:26:07
User entered '123.2' kg	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User accepted default value 'Pre-Dose (PREDOSE)'	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:36:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Aug 2020 16:36:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:35:15
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered '01 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered '08:47' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered '01 Aug 2020 08:47'	System	01 Aug 2020 16:36:08
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered '36.7' C reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered 'Other (Other)' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered 'tympanic' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered '78' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered 'bpm'	System	01 Aug 2020 16:36:08
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered '24' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered 'breaths/min'	System	01 Aug 2020 16:36:08
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered '144' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered 'mmHg'	System	01 Aug 2020 16:36:08
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered '90' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:36:08
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered 'mmHg'	System	01 Aug 2020 16:36:08
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:59

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User closed query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 12:17:28
Query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' answered with 'confirm correct' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 15:01:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:01:44
User opened query 'Per CDM: Please remove the units "cm,kg" recorded in the data fields Height and Weight as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:04
User closed query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:04
Query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:44:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:44:11
User opened query 'Per CDM: Per CCG, Pages 15-16, Height should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:25:57
User entered '185.0' cm	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:18:59

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 15:01:44
User closed query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:48:19
Query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' answered with 'updated' (Site from DM).	Ashley Bell (b) (4)	02 Sep 2020 21:44:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Ashley Bell (b) (4)	02 Sep 2020 21:44:11
User opened query 'Per CDM: Per CCG, Pages 15-16, Weight should be marked as "ND". Please update accordingly ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 12:26:07
User entered '123.2' kg	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User accepted default value 'Post-Dose (POSTDOSE)'	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:37:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Aug 2020 16:37:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:35:15
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered '01 Aug 2020' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 18:25:28
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol correct' (Site from System).	Ashley Bell (b) (4)	01 Aug 2020 16:37:28
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		01 Aug 2020 16:37:16
User entered '10:42' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered '01 Aug 2020 10:42'	System	01 Aug 2020 16:37:16
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered '37.0' C reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered 'Other (Other)' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered 'tympanic' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered '71' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered 'bpm'	System	01 Aug 2020 16:37:16
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered '15' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered 'breaths/min'	System	01 Aug 2020 16:37:16
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered '132' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered 'mmHg'	System	01 Aug 2020 16:37:16
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:12
User entered '100' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:37:16
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered 'mmHg'	System	01 Aug 2020 16:37:16
User entered empty.	System	01 Aug 2020 16:35:15

US3272026

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:07
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:37:52

US3272026

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:07
User entered '01 Aug 2020'	Ashley Bell (b) (4)	01 Aug 2020 16:37:52

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:17
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	15 Aug 2020 14:33:18
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	15 Aug 2020 14:33:18
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	01 Aug 2020 15:17:46
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:46

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:17
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:46

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:17
User entered empty.	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:46

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered 'MRNA-1273 OR PLACEBO'	System	01 Aug 2020 15:17:46

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:17
User entered '01 Aug 2020'	Kayla Flege (b) (4) (b) (4)	01 Aug 2020 15:17:46

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:17
User entered '10:10'	Kayla Flege (b) (4)	01 Aug 2020 15:17:46
	(b) (4)	

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered '01 Aug 2020 10:10'	System	01 Aug 2020 15:17:46

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:17
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Ashley Bell (b) (4)	15 Aug 2020 14:33:18
User entered empty.	Kayla Flege (b) (4)	01 Aug 2020 15:17:46
	(b) (4)	

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
DataPoint Verified.		21 Aug 2020 15:58:17
User entered 'ONCE'	System	01 Aug 2020 15:17:46

US3272026

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered 'INTRAMUSCULAR'	System	01 Aug 2020 15:17:46

US3272026

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:50
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:38:25

US3272026

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:50
User entered '01 Aug 2020'	Ashley Bell (b) (4)	01 Aug 2020 16:38:25

US3272026

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:50
User entered '09:26'	Ashley Bell (b) (4)	01 Aug 2020 16:38:25

US3272026

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered '01 Aug 2020 09:26'	System	01 Aug 2020 16:38:25

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:18:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:13:57
User entered '01 Aug 2020'	Ashley Bell (b) (4)	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Ashley Bell (b) (4)	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:19:03
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:19:03
User entered '09:20'	Ashley Bell (b) (4)	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered '01 Aug 2020 09:20'	System	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Ashley Bell (b) (4)	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:19:03
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:38:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Aug 2020 16:38:51
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bell (b) (4)	01 Aug 2020 16:38:51
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 16:38:46
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:19:03
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:59

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered empty.	System	01 Aug 2020 16:38:46

US3272026

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 17:52:16
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:44:43

US3272026

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:17:06
User entered 'I'	System	01 Aug 2020 16:44:43

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:49:58', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '515ed730-f1e6-4fcc-bd5c-12c768f7c6e9' User entered 'Yes (Y)'	System	01 Aug 2020 15:50:25
	System	01 Aug 2020 15:50:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:11', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '515ed730-f1e6-4fcc-bd5c-12c768f7c6e9' User entered '98.2'	System	01 Aug 2020 15:50:25
	System	01 Aug 2020 15:50:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:15', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '515ed730-f1e6-4fcc-bd5c-12c768f7c6e9'	System	01 Aug 2020 15:50:25
User entered 'No (N)'	System	01 Aug 2020 15:50:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:23', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '515ed730-f1e6-4fcc-bd5c-12c768f7c6e9' User entered '01 Aug 2020 10:50'	System	01 Aug 2020 15:50:25
	System	01 Aug 2020 15:50:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '01 Aug 2020 10:30'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '01 Aug 2020 13:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T00:59:49', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '0f9e8182-4ded-47a1-b9f3-b35120a29166' User entered 'Yes (Y)'	System	02 Aug 2020 06:03:44
	System	02 Aug 2020 06:03:44

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:03:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '0f9e8182-4ded-47a1-b9f3-b35120a29166' User entered '98.2'	System	02 Aug 2020 06:03:44
	System	02 Aug 2020 06:03:44

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:03:34', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '0f9e8182-4ded-47a1-b9f3-b35120a29166'	System	02 Aug 2020 06:03:44
User entered 'No (N)'	System	02 Aug 2020 06:03:44

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:03:40', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '0f9e8182-4ded-47a1-b9f3-b35120a29166' User entered '02 Aug 2020 01:03'	System	02 Aug 2020 06:03:44
	System	02 Aug 2020 06:03:44

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '01 Aug 2020 13:55'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 2'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:04', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8f16ed-e665-41e4-a4c9-38c3bf039d8d' User entered 'Yes (Y)'	System	03 Aug 2020 03:06:33
	System	03 Aug 2020 03:06:33

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:10', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8f16ed-e665-41e4-a4c9-38c3bf039d8d' User entered '97.3'	System	03 Aug 2020 03:06:33
	System	03 Aug 2020 03:06:33

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:21', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8f16ed-e665-41e4-a4c9-38c3bf039d8d' User entered 'No (N)'	System	03 Aug 2020 03:06:33
	System	03 Aug 2020 03:06:33

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8f16ed-e665-41e4-a4c9-38c3bf039d8d' User entered '02 Aug 2020 22:06'	System	03 Aug 2020 03:06:33
	System	03 Aug 2020 03:06:33

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 3'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:07:24', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6d356c6d-fbac-4918-9922-875e1482d19c' User entered 'Yes (Y)'	System	04 Aug 2020 02:07:50
	System	04 Aug 2020 02:07:50

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:07:40', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6d356c6d-fbac-4918-9922-875e1482d19c' User entered '96.9'	System	04 Aug 2020 02:07:50
	System	04 Aug 2020 02:07:50

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:07:43', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6d356c6d-fbac-4918-9922-875e1482d19c' User entered 'No (N)'	System	04 Aug 2020 02:07:50
	System	04 Aug 2020 02:07:50

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:07:48', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6d356c6d-fbac-4918-9922-875e1482d19c' User entered '03 Aug 2020 21:07'	System	04 Aug 2020 02:07:50
	System	04 Aug 2020 02:07:50

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 4'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:08', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1130fafe-6e67-460e-9139-cb4bbd031317' User entered 'Yes (Y)'	System	05 Aug 2020 01:41:25
	System	05 Aug 2020 01:41:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:15', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1130fafe-6e67-460e-9139-cb4bbd031317' User entered '97.8'	System	05 Aug 2020 01:41:25
	System	05 Aug 2020 01:41:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1130fafe-6e67-460e-9139-cb4bbd031317'	System	05 Aug 2020 01:41:25
User entered 'No (N)'	System	05 Aug 2020 01:41:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:22', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1130fafe-6e67-460e-9139-cb4bbd031317' User entered '04 Aug 2020 20:41'	System	05 Aug 2020 01:41:25
	System	05 Aug 2020 01:41:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 5'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8fcacd-7bab-492c-b47b-ad1e247adf63' User entered 'Yes (Y)'	System	06 Aug 2020 02:26:36
	System	06 Aug 2020 02:26:36

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:23', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8fcacd-7bab-492c-b47b-ad1e247adf63' User entered '98.1'	System	06 Aug 2020 02:26:36
	System	06 Aug 2020 02:26:36

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8fcacd-7bab-492c-b47b-ad1e247adf63'	System	06 Aug 2020 02:26:36
User entered 'No (N)'	System	06 Aug 2020 02:26:36

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:31', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1f8fcacd-7bab-492c-b47b-ad1e247adf63'	System	06 Aug 2020 02:26:36
User entered '05 Aug 2020 21:26'	System	06 Aug 2020 02:26:36

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 6'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:16', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4cf56589-e516-4e47-98bc-c7352bb4225e' User entered 'Yes (Y)'	System	07 Aug 2020 01:02:15
	System	07 Aug 2020 01:02:15

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:21', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4cf56589-e516-4e47-98bc-c7352bb4225e' User entered '98.1'	System	07 Aug 2020 01:02:15
	System	07 Aug 2020 01:02:15

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4cf56589-e516-4e47-98bc-c7352bb4225e'	System	07 Aug 2020 01:02:15
User entered 'No (N)'	System	07 Aug 2020 01:02:15

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:30', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4cf56589-e516-4e47-98bc-c7352bb4225e'	System	07 Aug 2020 01:02:15
User entered '06 Aug 2020 18:56'	System	07 Aug 2020 01:02:15

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 7'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:08', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '20bc1072-075a-4a28-aa69-7abbe6a0ca1d' User entered 'Yes (Y)'	System	07 Aug 2020 23:26:25
	System	07 Aug 2020 23:26:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:17', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '20bc1072-075a-4a28-aa69-7abbe6a0ca1d' User entered '98.3'	System	07 Aug 2020 23:26:25
	System	07 Aug 2020 23:26:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:21', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '20bc1072-075a-4a28-aa69-7abbe6a0ca1d'	System	07 Aug 2020 23:26:25
User entered 'No (N)'	System	07 Aug 2020 23:26:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:23', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '20bc1072-075a-4a28-aa69-7abbe6a0ca1d' User entered '07 Aug 2020 17:26'	System	07 Aug 2020 23:26:25
	System	07 Aug 2020 23:26:25

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:31', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '37941e26-7484-49a7-9529-666cd3c60eba' User entered 'None (1)'	System	01 Aug 2020 15:50:49
	System	01 Aug 2020 15:50:49

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:35', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '37941e26-7484-49a7-9529-666cd3c60eba' User entered 'No (N)'	System	01 Aug 2020 15:50:49
	System	01 Aug 2020 15:50:49

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:39', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '37941e26-7484-49a7-9529-666cd3c60eba' User entered 'No (N)'	System	01 Aug 2020 15:50:49
	System	01 Aug 2020 15:50:49

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:43', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '37941e26-7484-49a7-9529-666cd3c60eba' User entered 'None (1)'	System	01 Aug 2020 15:50:49
	System	01 Aug 2020 15:50:49

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:47', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '37941e26-7484-49a7-9529-666cd3c60eba' User entered '01 Aug 2020 10:50'	System	01 Aug 2020 15:50:49
	System	01 Aug 2020 15:50:49

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '01 Aug 2020 10:30'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '01 Aug 2020 13:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:03:46', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '89fb8046-9e24-41bd-9978-cda460ffbdee'	System	02 Aug 2020 06:04:10
User entered 'None (1)'	System	02 Aug 2020 06:04:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:03:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '89fb8046-9e24-41bd-9978-cda460ffbdee'	System	02 Aug 2020 06:04:10
User entered 'No (N)'	System	02 Aug 2020 06:04:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:03:57', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '89fb8046-9e24-41bd-9978-cda460ffbdee' User entered 'No (N)'	System	02 Aug 2020 06:04:10
	System	02 Aug 2020 06:04:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:05', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '89fb8046-9e24-41bd-9978-cda460ffbdee'	System	02 Aug 2020 06:04:10
User entered 'None (1)'	System	02 Aug 2020 06:04:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:09', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '89fb8046-9e24-41bd-9978-cda460ffbdee' User entered '02 Aug 2020 01:04'	System	02 Aug 2020 06:04:10
	System	02 Aug 2020 06:04:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '01 Aug 2020 13:55'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 2'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:34', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '2c940d89-b198-4293-b5f2-766cb6027bf8' User entered 'None (1)'	System	03 Aug 2020 03:07:03
	System	03 Aug 2020 03:07:03

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:38', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '2c940d89-b198-4293-b5f2-766cb6027bf8' User entered 'No (N)'	System	03 Aug 2020 03:07:03
	System	03 Aug 2020 03:07:03

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:44', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '2c940d89-b198-4293-b5f2-766cb6027bf8' User entered 'No (N)'	System	03 Aug 2020 03:07:03
	System	03 Aug 2020 03:07:03

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:06:51', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '2c940d89-b198-4293-b5f2-766cb6027bf8' User entered 'None (1)'	System	03 Aug 2020 03:07:03
	System	03 Aug 2020 03:07:03

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:07:01', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '2c940d89-b198-4293-b5f2-766cb6027bf8' User entered '02 Aug 2020 22:07'	System	03 Aug 2020 03:07:03
	System	03 Aug 2020 03:07:03

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 3'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:07:55', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70ec1a28-94dd-4837-812f-aca7906eb25f' User entered 'None (1)'	System	04 Aug 2020 02:08:10
	System	04 Aug 2020 02:08:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:07:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70ec1a28-94dd-4837-812f-aca7906eb25f' User entered 'No (N)'	System	04 Aug 2020 02:08:10
	System	04 Aug 2020 02:08:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:02', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70ec1a28-94dd-4837-812f-aca7906eb25f' User entered 'No (N)'	System	04 Aug 2020 02:08:10
	System	04 Aug 2020 02:08:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:05', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70ec1a28-94dd-4837-812f-aca7906eb25f' User entered 'None (1)'	System	04 Aug 2020 02:08:10
	System	04 Aug 2020 02:08:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:08', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70ec1a28-94dd-4837-812f-aca7906eb25f' User entered '03 Aug 2020 21:08'	System	04 Aug 2020 02:08:10
	System	04 Aug 2020 02:08:10

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 4'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:26', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '14201a4a-4de9-4a27-9e1a-6b00bc4304a8' User entered 'None (1)'	System	05 Aug 2020 01:41:42
	System	05 Aug 2020 01:41:42

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '14201a4a-4de9-4a27-9e1a-6b00bc4304a8' User entered 'No (N)'	System	05 Aug 2020 01:41:42
	System	05 Aug 2020 01:41:42

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:32', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '14201a4a-4de9-4a27-9e1a-6b00bc4304a8' User entered 'No (N)'	System	05 Aug 2020 01:41:42
	System	05 Aug 2020 01:41:42

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:35', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '14201a4a-4de9-4a27-9e1a-6b00bc4304a8' User entered 'None (1)'	System	05 Aug 2020 01:41:42
	System	05 Aug 2020 01:41:42

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:38', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '14201a4a-4de9-4a27-9e1a-6b00bc4304a8' User entered '04 Aug 2020 20:41'	System	05 Aug 2020 01:41:42
	System	05 Aug 2020 01:41:42

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 5'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:35', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'be91b033-1760-47eb-b3c5-fbf7dbd7b5b6'	System	06 Aug 2020 02:26:48
User entered 'None (1)'	System	06 Aug 2020 02:26:48

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:39', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'be91b033-1760-47eb-b3c5-fbf7dbd7b5b6'	System	06 Aug 2020 02:26:48
User entered 'No (N)'	System	06 Aug 2020 02:26:48

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:41', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'be91b033-1760-47eb-b3c5-fbf7dbd7b5b6' User entered 'No (N)'	System	06 Aug 2020 02:26:48
	System	06 Aug 2020 02:26:48

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:44', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'be91b033-1760-47eb-b3c5-fbf7dbd7b5b6'	System	06 Aug 2020 02:26:48
User entered 'None (1)'	System	06 Aug 2020 02:26:48

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:47', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'be91b033-1760-47eb-b3c5-fbf7dbd7b5b6' User entered '05 Aug 2020 21:26'	System	06 Aug 2020 02:26:48
	System	06 Aug 2020 02:26:48

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 6'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:36', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '253131d6-6d72-44a8-9356-af76fe60e159'	System	07 Aug 2020 01:02:23
User entered 'None (1)'	System	07 Aug 2020 01:02:23

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:41', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '253131d6-6d72-44a8-9356-af76fe60e159'	System	07 Aug 2020 01:02:23
User entered 'No (N)'	System	07 Aug 2020 01:02:23

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:44', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '253131d6-6d72-44a8-9356-af76fe60e159' User entered 'No (N)'	System	07 Aug 2020 01:02:23
	System	07 Aug 2020 01:02:23

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:47', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '253131d6-6d72-44a8-9356-af76fe60e159'	System	07 Aug 2020 01:02:23
User entered 'None (1)'	System	07 Aug 2020 01:02:23

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '253131d6-6d72-44a8-9356-af76fe60e159' User entered '06 Aug 2020 18:56'	System	07 Aug 2020 01:02:23
	System	07 Aug 2020 01:02:23

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 7'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '952b74f3-608f-4208-b9b9-31b2228b3187' User entered 'None (1)'	System	07 Aug 2020 23:26:50
	System	07 Aug 2020 23:26:50

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:32', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '952b74f3-608f-4208-b9b9-31b2228b3187'	System	07 Aug 2020 23:26:50
User entered 'No (N)'	System	07 Aug 2020 23:26:50

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:36', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '952b74f3-608f-4208-b9b9-31b2228b3187'	System	07 Aug 2020 23:26:50
User entered 'No (N)'	System	07 Aug 2020 23:26:50

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:42', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '952b74f3-608f-4208-b9b9-31b2228b3187'	System	07 Aug 2020 23:26:50
User entered 'None (1)'	System	07 Aug 2020 23:26:50

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:45', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '952b74f3-608f-4208-b9b9-31b2228b3187' User entered '07 Aug 2020 17:26'	System	07 Aug 2020 23:26:50
	System	07 Aug 2020 23:26:50

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:53', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb' User entered 'None (0)'	System	01 Aug 2020 15:51:15
	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:55', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb' User entered 'None (0)'	System	01 Aug 2020 15:51:15
	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:50:58', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb' User entered 'None (0)'	System	01 Aug 2020 15:51:15
	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:51:01', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb' User entered 'None (0)'	System	01 Aug 2020 15:51:15
	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:51:04', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb' User entered 'None (0)'	System	01 Aug 2020 15:51:15
	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:51:06', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb' User entered 'None (0)'	System	01 Aug 2020 15:51:15
	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:51:11', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb' User entered 'No (N)'	System	01 Aug 2020 15:51:15
	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-01T10:51:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '6c0cac82-bd2a-453a-a83f-def3474e5beb' User entered '01 Aug 2020 10:51'	System	01 Aug 2020 15:51:15
	System	01 Aug 2020 15:51:15

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '01 Aug 2020 10:30'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '01 Aug 2020 13:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:16', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e' User entered 'None (0)'	System	02 Aug 2020 06:04:39
	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e' User entered 'None (0)'	System	02 Aug 2020 06:04:39
	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:22', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e' User entered 'None (0)'	System	02 Aug 2020 06:04:39
	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:25', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e' User entered 'None (0)'	System	02 Aug 2020 06:04:39
	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e' User entered 'None (0)'	System	02 Aug 2020 06:04:39
	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:30', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e' User entered 'None (0)'	System	02 Aug 2020 06:04:39
	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:35', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e' User entered 'No (N)'	System	02 Aug 2020 06:04:39
	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T01:04:37', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9aff5fa4-d9a1-4b27-bb90-c3ac9b4eba8e' User entered '02 Aug 2020 01:04'	System	02 Aug 2020 06:04:39
	System	02 Aug 2020 06:04:39

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '01 Aug 2020 13:55'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 2'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:07:13', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637' User entered 'None (0)'	System	03 Aug 2020 03:08:12
	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:07:39', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637' User entered 'None (0)'	System	03 Aug 2020 03:08:12
	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:07:42', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637' User entered 'None (0)'	System	03 Aug 2020 03:08:12
	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:07:52', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637' User entered 'None (0)'	System	03 Aug 2020 03:08:12
	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:08:00', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637' User entered 'None (0)'	System	03 Aug 2020 03:08:12
	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:08:03', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637' User entered 'None (0)'	System	03 Aug 2020 03:08:12
	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:08:07', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637'	System	03 Aug 2020 03:08:12
User entered 'No (N)'	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-02T22:08:10', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd96ac4ef-0bb7-426b-9cb8-760b5210e637'	System	03 Aug 2020 03:08:12
User entered '02 Aug 2020 22:08'	System	03 Aug 2020 03:08:12

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 3'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:13', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85' User entered 'None (0)'	System	04 Aug 2020 02:08:45
	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85' User entered 'None (0)'	System	04 Aug 2020 02:08:45
	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:23', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85' User entered 'None (0)'	System	04 Aug 2020 02:08:45
	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85' User entered 'None (0)'	System	04 Aug 2020 02:08:45
	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:30', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85' User entered 'None (0)'	System	04 Aug 2020 02:08:45
	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:34', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85' User entered 'None (0)'	System	04 Aug 2020 02:08:45
	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:39', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85' User entered 'No (N)'	System	04 Aug 2020 02:08:45
	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-03T21:08:42', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dc8b37a2-4be3-4f62-9e96-8db7c8c5cf85' User entered '03 Aug 2020 21:08'	System	04 Aug 2020 02:08:45
	System	04 Aug 2020 02:08:45

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 4'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:42', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9' User entered 'None (0)'	System	05 Aug 2020 01:42:02
	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:44', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9' User entered 'None (0)'	System	05 Aug 2020 01:42:02
	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:46', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9' User entered 'None (0)'	System	05 Aug 2020 01:42:02
	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:49', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9' User entered 'None (0)'	System	05 Aug 2020 01:42:02
	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:51', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9' User entered 'None (0)'	System	05 Aug 2020 01:42:02
	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:53', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9' User entered 'None (0)'	System	05 Aug 2020 01:42:02
	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:56', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9' User entered 'No (N)'	System	05 Aug 2020 01:42:02
	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-04T20:41:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd903fb30-6cff-4e0e-a894-77a0c8d761a9' User entered '04 Aug 2020 20:41'	System	05 Aug 2020 01:42:02
	System	05 Aug 2020 01:42:02

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 5'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520' User entered 'None (0)'	System	06 Aug 2020 02:27:10
	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:52', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520' User entered 'None (0)'	System	06 Aug 2020 02:27:10
	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:54', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520' User entered 'None (0)'	System	06 Aug 2020 02:27:10
	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:26:56', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520' User entered 'None (0)'	System	06 Aug 2020 02:27:10
	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:27:02', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520' User entered 'None (0)'	System	06 Aug 2020 02:27:10
	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:27:05', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520' User entered 'None (0)'	System	06 Aug 2020 02:27:10
	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:27:07', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520' User entered 'No (N)'	System	06 Aug 2020 02:27:10
	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-05T21:27:09', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1d0aebea-7563-4a3b-acd7-5d54eb5dd520' User entered '05 Aug 2020 21:27'	System	06 Aug 2020 02:27:10
	System	06 Aug 2020 02:27:10

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 6'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:56:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27'	System	07 Aug 2020 01:02:24
User entered 'None (0)'	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:57:02', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27'	System	07 Aug 2020 01:02:24
User entered 'None (0)'	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:57:07', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27' User entered 'None (0)'	System	07 Aug 2020 01:02:24
	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:57:09', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27' User entered 'None (0)'	System	07 Aug 2020 01:02:24
	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:57:12', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27' User entered 'None (0)'	System	07 Aug 2020 01:02:24
	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:57:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27'	System	07 Aug 2020 01:02:24
User entered 'None (0)'	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:57:24', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27'	System	07 Aug 2020 01:02:24
User entered 'No (N)'	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-06T18:57:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3b35cf32-7a45-45f1-aba7-e6c5d35dfc27' User entered '06 Aug 2020 18:57'	System	07 Aug 2020 01:02:24
	System	07 Aug 2020 01:02:24

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 7'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:26:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e' User entered 'None (0)'	System	07 Aug 2020 23:27:32
	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:27:02', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e' User entered 'None (0)'	System	07 Aug 2020 23:27:32
	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:27:04', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e' User entered 'None (0)'	System	07 Aug 2020 23:27:32
	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:27:10', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e' User entered 'None (0)'	System	07 Aug 2020 23:27:32
	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:27:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e' User entered 'None (0)'	System	07 Aug 2020 23:27:32
	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:27:17', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e' User entered 'None (0)'	System	07 Aug 2020 23:27:32
	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:27:26', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e' User entered 'No (N)'	System	07 Aug 2020 23:27:32
	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-08-07T17:27:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f421fffe-cb9c-4f75-a226-8cb423b5602e' User entered '07 Aug 2020 17:27'	System	07 Aug 2020 23:27:32
	System	07 Aug 2020 23:27:32

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '07 Aug 2020 12:00'	System	01 Aug 2020 15:17:46

US3272026

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '08 Aug 2020 11:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:35
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:14:54

US3272026

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:35
User entered '10 Aug 2020'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:14:54

US3272026

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:35
User entered 'Contact Made (CONTACT MADE)'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:14:54

US3272026

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:35
User entered empty.	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:14:54

US3272026

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:19:15
User entered 'Yes (Y)'	Kayla Flege (b) (4) (b) (4)	14 Aug 2020 00:15:27

US3272026

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:50:41
User entered 'I'	System	14 Aug 2020 00:15:27

US3272026

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:49:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:19:30
User entered 'Yes (Y)'		21 Aug 2020 18:36:09

US3272026

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:49:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:19:30
User entered '17 Aug 2020'		21 Aug 2020 18:36:09

US3272026

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:49:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:19:30
User entered 'Contact Made (CONTACT MADE)'		21 Aug 2020 18:36:09

US3272026

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:49:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:19:30
User entered empty.		21 Aug 2020 18:36:09

US3272026

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:49:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:19:34
User entered 'Yes (Y)'		21 Aug 2020 18:35:56

US3272026

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:49:12
User entered 'I'	System	21 Aug 2020 18:35:56

US3272026

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:34:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:19:39
User entered 'Yes (Y)'		28 Aug 2020 19:06:04

US3272026

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:34:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:19:39
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Aug 2020 19:06:31
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	28 Aug 2020 19:06:31
User entered '24 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Aug 2020 19:06:31
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	28 Aug 2020 19:06:04
User entered '26 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 19:06:04

US3272026

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:34:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:19:39
User entered 'Contact Made (CONTACT MADE)'		28 Aug 2020 19:06:04

US3272026

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:34:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:19:39
User entered empty.		28 Aug 2020 19:06:04

US3272026

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:34:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:19:43
User entered 'Yes (Y)'		28 Aug 2020 19:06:40

US3272026

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:34:46
User entered 'I'	System	28 Aug 2020 19:06:40

US3272026

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:20:23
User entered 'Yes (Y)'		08 Sep 2020 23:11:27

US3272026

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:20:23
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).		29 Sep 2020 09:30:45
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'confirm correct' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 18:14:21
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 16:31:24
Amendment Manager: User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	16 Sep 2020 23:40:21
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 17:27:11
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'PROTOCOL DEVIATION NOTED' (Site from System).		08 Sep 2020 23:12:48
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	08 Sep 2020 23:11:27
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 23:11:27

US3272026

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:20:23
User entered 'Clinic (Clinic)'		08 Sep 2020 23:11:27

US3272026

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered 'VISIT2'	System	08 Sep 2020 23:11:27

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User accepted default value 'Pre-Dose (PREDOSE)'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered 'Yes (Y)'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered '8 Sep 2020'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered '10:26'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered '8 Sep 2020 10:26'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered '37.0' C		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered 'Oral (Oral)'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered empty.		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered '77'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered 'bpm'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered '18'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered 'breaths/min'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered '137'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered 'mmHg'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered '88'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:18:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered 'mmHg'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User accepted default value 'Post-Dose (POSTDOSE)'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered 'Yes (Y)'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered '8 Sep 2020'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered '12:05'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered '8 Sep 2020 12:05'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered '36.6' C		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered 'Oral (Oral)'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered empty.		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered '73'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered 'bpm'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered '14'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered 'breaths/min'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered '138'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered 'mmHg'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:47
User entered '88'		08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:18:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered 'mmHg'	System	08 Sep 2020 23:14:07

US3272026

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:52
User entered 'Yes (Y)'		08 Sep 2020 23:14:13

US3272026

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:52
User entered '8 Sep 2020'		08 Sep 2020 23:14:13

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:59
User entered 'Yes (Y)'	Kayla Flege (b) (4)	08 Sep 2020 16:42:30
	(b) (4)	

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:59
User entered empty.	Kayla Flege (b) (4)	08 Sep 2020 16:42:30
	(b) (4)	

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:59
User entered empty.	Kayla Flege (b) (4) (b) (4)	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:59
User entered '08 Sep 2020'	Kayla Flege (b) (4)	08 Sep 2020 16:42:30
	(b) (4)	

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:59
User entered '11:33'	Kayla Flege (b) (4)	08 Sep 2020 16:42:30
	(b) (4)	

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered '08 Sep 2020 11:33'	System	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:59
User entered 'Left Arm (LEFT ARM)'	Kayla Flege (b) (4) (b) (4)	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:21:59
User entered 'ONCE'	System	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:18:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 16:42:30

US3272026

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:22:05
User entered 'Yes (Y)'		08 Sep 2020 23:14:26

US3272026

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:22:05
User entered '8 Sep 2020'		08 Sep 2020 23:14:26

US3272026

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:22:05
User entered '10:46'		08 Sep 2020 23:14:26

US3272026

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered '8 Sep 2020 10:46'	System	08 Sep 2020 23:14:26

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:18:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:22:10
User entered '8 Sep 2020'		08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:22:10
User entered 'Yes (Y)'		08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:22:10
User entered '10:36'		08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered '8 Sep 2020 10:36'	System	08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:22:10
User entered 'No (N)'		08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:22:10
User entered empty.		08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered empty.	System	08 Sep 2020 23:14:38

US3272026

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:22:14
User entered 'Yes (Y)'		08 Sep 2020 23:14:43

US3272026

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:43:11
User entered '1'	System	08 Sep 2020 23:14:43

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:05:13', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '03d189c1-063f-484b-a8f0-f3a9b02bdeaa' User entered 'Yes (Y)'	System	08 Sep 2020 17:05:54
	System	08 Sep 2020 17:05:54

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:05:22', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '03d189c1-063f-484b-a8f0-f3a9b02bdeaa' User entered '97.9'	System	08 Sep 2020 17:05:54
	System	08 Sep 2020 17:05:54

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:05:26', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '03d189c1-063f-484b-a8f0-f3a9b02bdeaa' User entered 'No (N)'	System	08 Sep 2020 17:05:54
	System	08 Sep 2020 17:05:54

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:05:33', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '03d189c1-063f-484b-a8f0-f3a9b02bdeaa' User entered '08 Sep 2020 12:05'	System	08 Sep 2020 17:05:54
	System	08 Sep 2020 17:05:54

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '08 Sep 2020 11:53'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '08 Sep 2020 14:23'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:24:56', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '83584288-c081-451b-8f1a-29f99afd4d3c' User entered 'Yes (Y)'	System	09 Sep 2020 01:25:14
	System	09 Sep 2020 01:25:14

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:25:02', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '83584288-c081-451b-8f1a-29f99afd4d3c' User entered '97.5'	System	09 Sep 2020 01:25:14
	System	09 Sep 2020 01:25:14

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:25:06', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '83584288-c081-451b-8f1a-29f99afd4d3c' User entered 'No (N)'	System	09 Sep 2020 01:25:14
	System	09 Sep 2020 01:25:14

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:25:12', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '83584288-c081-451b-8f1a-29f99afd4d3c' User entered '08 Sep 2020 20:25'	System	09 Sep 2020 01:25:14
	System	09 Sep 2020 01:25:14

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '08 Sep 2020 15:18'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 2'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:02:46', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd038f6a9-c1c5-4167-9cb0-37f9f65dcb6f' User entered 'Yes (Y)'	System	09 Sep 2020 21:03:03
	System	09 Sep 2020 21:03:03

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:02:51', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd038f6a9-c1c5-4167-9cb0-37f9f65dcb6f' User entered '98.5'	System	09 Sep 2020 21:03:03
	System	09 Sep 2020 21:03:03

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:02:55', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd038f6a9-c1c5-4167-9cb0-37f9f65dcb6f' User entered 'No (N)'	System	09 Sep 2020 21:03:03
	System	09 Sep 2020 21:03:03

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:02:58', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'd038f6a9-c1c5-4167-9cb0-37f9f65dcb6f' User entered '09 Sep 2020 16:02'	System	09 Sep 2020 21:03:03
	System	09 Sep 2020 21:03:03

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 3'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:20', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '8bb15bcc-bac7-4d6f-b2f0-9bcb39942721' User entered 'Yes (Y)'	System	11 Sep 2020 04:40:39
	System	11 Sep 2020 04:40:39

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '8bb15bcc-bac7-4d6f-b2f0-9bcb39942721' User entered '97.9'	System	11 Sep 2020 04:40:39
	System	11 Sep 2020 04:40:39

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:33', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '8bb15bcc-bac7-4d6f-b2f0-9bcb39942721' User entered 'No (N)'	System	11 Sep 2020 04:40:39
	System	11 Sep 2020 04:40:39

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:37', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '8bb15bcc-bac7-4d6f-b2f0-9bcb39942721' User entered '10 Sep 2020 23:40'	System	11 Sep 2020 04:40:39
	System	11 Sep 2020 04:40:39

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 4'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:25:37', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '96b240d6-e04e-4bbf-8cf0-ec5ccb391dcd' User entered 'Yes (Y)'	System	11 Sep 2020 20:25:55
	System	11 Sep 2020 20:25:55

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:25:46', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '96b240d6-e04e-4bbf-8cf0-ec5ccb391dcd' User entered '98.1'	System	11 Sep 2020 20:25:55
	System	11 Sep 2020 20:25:55

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:25:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '96b240d6-e04e-4bbf-8cf0-ec5ccb391dcd' User entered 'No (N)'	System	11 Sep 2020 20:25:55
	System	11 Sep 2020 20:25:55

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:25:52', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '96b240d6-e04e-4bbf-8cf0-ec5ccb391dcd' User entered '11 Sep 2020 15:25'	System	11 Sep 2020 20:25:55
	System	11 Sep 2020 20:25:55

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 5'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:11:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'fddade9a-35ea-4bf0-82d5-99a9e752ce38' User entered 'Yes (Y)'	System	12 Sep 2020 17:12:15
	System	12 Sep 2020 17:12:15

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:06', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'fddade9a-35ea-4bf0-82d5-99a9e752ce38' User entered '97.9'	System	12 Sep 2020 17:12:15
	System	12 Sep 2020 17:12:15

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:09', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'fddade9a-35ea-4bf0-82d5-99a9e752ce38'	System	12 Sep 2020 17:12:15
User entered 'No (N)'	System	12 Sep 2020 17:12:15

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:11', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'fddade9a-35ea-4bf0-82d5-99a9e752ce38' User entered '12 Sep 2020 12:12'	System	12 Sep 2020 17:12:15
	System	12 Sep 2020 17:12:15

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 6'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:21', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '942c8e2c-12d9-45c4-89f8-8eb95f62d890' User entered 'Yes (Y)'	System	13 Sep 2020 17:02:19
	System	13 Sep 2020 17:02:19

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:30', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '942c8e2c-12d9-45c4-89f8-8eb95f62d890' User entered '97.9'	System	13 Sep 2020 17:02:19
	System	13 Sep 2020 17:02:19

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:34', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '942c8e2c-12d9-45c4-89f8-8eb95f62d890' User entered 'No (N)'	System	13 Sep 2020 17:02:19
	System	13 Sep 2020 17:02:19

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:36', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '942c8e2c-12d9-45c4-89f8-8eb95f62d890' User entered '13 Sep 2020 12:01'	System	13 Sep 2020 17:02:19
	System	13 Sep 2020 17:02:19

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 7'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:08', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9a717db6-89e1-4430-a3bd-a51929adc6d1' User entered 'Yes (Y)'	System	14 Sep 2020 23:46:24
	System	14 Sep 2020 23:46:24

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:13', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9a717db6-89e1-4430-a3bd-a51929adc6d1' User entered '98.1'	System	14 Sep 2020 23:46:24
	System	14 Sep 2020 23:46:24

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:18', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9a717db6-89e1-4430-a3bd-a51929adc6d1' User entered 'No (N)'	System	14 Sep 2020 23:46:24
	System	14 Sep 2020 23:46:24

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:20', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9a717db6-89e1-4430-a3bd-a51929adc6d1' User entered '14 Sep 2020 18:46'	System	14 Sep 2020 23:46:24
	System	14 Sep 2020 23:46:24

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:08', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3530c0dd-5ab4-43c5-b7e7-76058cfba106' User entered 'None (1)'	System	08 Sep 2020 17:09:24
	System	08 Sep 2020 17:09:24

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:11', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3530c0dd-5ab4-43c5-b7e7-76058cfba106' User entered 'No (N)'	System	08 Sep 2020 17:09:24
	System	08 Sep 2020 17:09:24

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:15', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3530c0dd-5ab4-43c5-b7e7-76058cfba106' User entered 'No (N)'	System	08 Sep 2020 17:09:24
	System	08 Sep 2020 17:09:24

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:18', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3530c0dd-5ab4-43c5-b7e7-76058cfba106' User entered 'None (1)'	System	08 Sep 2020 17:09:24
	System	08 Sep 2020 17:09:24

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:22', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3530c0dd-5ab4-43c5-b7e7-76058cfba106' User entered '08 Sep 2020 12:09'	System	08 Sep 2020 17:09:24
	System	08 Sep 2020 17:09:24

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '08 Sep 2020 11:53'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '08 Sep 2020 14:23'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:25:16', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ab1a2960-0f62-4aee-9616-6ad23d75ceea' User entered 'None (1)'	System	09 Sep 2020 01:26:03
	System	09 Sep 2020 01:26:03

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:25:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ab1a2960-0f62-4aee-9616-6ad23d75ceea' User entered 'No (N)'	System	09 Sep 2020 01:26:03
	System	09 Sep 2020 01:26:03

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:25:25', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ab1a2960-0f62-4aee-9616-6ad23d75ceea' User entered 'No (N)'	System	09 Sep 2020 01:26:03
	System	09 Sep 2020 01:26:03

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:25:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ab1a2960-0f62-4aee-9616-6ad23d75ceea' User entered 'None (1)'	System	09 Sep 2020 01:26:03
	System	09 Sep 2020 01:26:03

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:26:00', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ab1a2960-0f62-4aee-9616-6ad23d75ceea' User entered '08 Sep 2020 20:26'	System	09 Sep 2020 01:26:03
	System	09 Sep 2020 01:26:03

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '08 Sep 2020 15:18'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 2'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:03', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '823bfa3e-360c-4de9-ac60-538d39ac1ae6'	System	09 Sep 2020 21:03:18
User entered 'None (1)'	System	09 Sep 2020 21:03:18

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:07', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '823bfa3e-360c-4de9-ac60-538d39ac1ae6' User entered 'No (N)'	System	09 Sep 2020 21:03:18
	System	09 Sep 2020 21:03:18

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:10', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '823bfa3e-360c-4de9-ac60-538d39ac1ae6' User entered 'No (N)'	System	09 Sep 2020 21:03:18
	System	09 Sep 2020 21:03:18

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:15', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '823bfa3e-360c-4de9-ac60-538d39ac1ae6' User entered 'None (1)'	System	09 Sep 2020 21:03:18
	System	09 Sep 2020 21:03:18

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:17', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '823bfa3e-360c-4de9-ac60-538d39ac1ae6' User entered '09 Sep 2020 16:03'	System	09 Sep 2020 21:03:18
	System	09 Sep 2020 21:03:18

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 3'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:42', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5d492065-f492-4d50-a302-8cbfdd6a6e12'	System	11 Sep 2020 04:40:56
User entered 'None (1)'	System	11 Sep 2020 04:40:56

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:45', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5d492065-f492-4d50-a302-8cbfdd6a6e12' User entered 'No (N)'	System	11 Sep 2020 04:40:56
	System	11 Sep 2020 04:40:56

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:47', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5d492065-f492-4d50-a302-8cbfdd6a6e12' User entered 'No (N)'	System	11 Sep 2020 04:40:56
	System	11 Sep 2020 04:40:56

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:52', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5d492065-f492-4d50-a302-8cbfdd6a6e12'	System	11 Sep 2020 04:40:56
User entered 'None (1)'	System	11 Sep 2020 04:40:56

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:40:55', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5d492065-f492-4d50-a302-8cbfdd6a6e12' User entered '10 Sep 2020 23:40'	System	11 Sep 2020 04:40:56
	System	11 Sep 2020 04:40:56

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 4'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:25:56', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '16057414-9887-4cf3-9e67-eae4525251ee' User entered 'None (1)'	System	11 Sep 2020 20:26:09
	System	11 Sep 2020 20:26:09

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:25:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '16057414-9887-4cf3-9e67-eae4525251ee' User entered 'No (N)'	System	11 Sep 2020 20:26:09
	System	11 Sep 2020 20:26:09

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:02', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '16057414-9887-4cf3-9e67-eae4525251ee' User entered 'No (N)'	System	11 Sep 2020 20:26:09
	System	11 Sep 2020 20:26:09

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:05', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '16057414-9887-4cf3-9e67-eae4525251ee' User entered 'None (1)'	System	11 Sep 2020 20:26:09
	System	11 Sep 2020 20:26:09

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:08', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '16057414-9887-4cf3-9e67-eae4525251ee' User entered '11 Sep 2020 15:26'	System	11 Sep 2020 20:26:09
	System	11 Sep 2020 20:26:09

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 5'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '935e0f07-6350-4ac6-b849-a709d0480391' User entered 'None (1)'	System	12 Sep 2020 17:12:26
	System	12 Sep 2020 17:12:26

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:16', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '935e0f07-6350-4ac6-b849-a709d0480391' User entered 'No (N)'	System	12 Sep 2020 17:12:26
	System	12 Sep 2020 17:12:26

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '935e0f07-6350-4ac6-b849-a709d0480391' User entered 'No (N)'	System	12 Sep 2020 17:12:26
	System	12 Sep 2020 17:12:26

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:21', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '935e0f07-6350-4ac6-b849-a709d0480391' User entered 'None (1)'	System	12 Sep 2020 17:12:26
	System	12 Sep 2020 17:12:26

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:23', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '935e0f07-6350-4ac6-b849-a709d0480391' User entered '12 Sep 2020 12:12'	System	12 Sep 2020 17:12:26
	System	12 Sep 2020 17:12:26

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 6'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:40', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4e074d19-fd35-4e86-a017-c24040f4a52d' User entered 'None (1)'	System	13 Sep 2020 17:02:37
	System	13 Sep 2020 17:02:37

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:42', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4e074d19-fd35-4e86-a017-c24040f4a52d' User entered 'No (N)'	System	13 Sep 2020 17:02:37
	System	13 Sep 2020 17:02:37

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:46', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4e074d19-fd35-4e86-a017-c24040f4a52d' User entered 'No (N)'	System	13 Sep 2020 17:02:37
	System	13 Sep 2020 17:02:37

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:48', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4e074d19-fd35-4e86-a017-c24040f4a52d' User entered 'None (1)'	System	13 Sep 2020 17:02:37
	System	13 Sep 2020 17:02:37

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4e074d19-fd35-4e86-a017-c24040f4a52d' User entered '13 Sep 2020 12:01'	System	13 Sep 2020 17:02:37
	System	13 Sep 2020 17:02:37

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 7'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:24', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1386bfa2-da8a-43c6-b90b-1d830b958ef9' User entered 'None (1)'	System	14 Sep 2020 23:46:38
	System	14 Sep 2020 23:46:38

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:26', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1386bfa2-da8a-43c6-b90b-1d830b958ef9' User entered 'No (N)'	System	14 Sep 2020 23:46:38
	System	14 Sep 2020 23:46:38

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:28', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1386bfa2-da8a-43c6-b90b-1d830b958ef9' User entered 'No (N)'	System	14 Sep 2020 23:46:38
	System	14 Sep 2020 23:46:38

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:30', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1386bfa2-da8a-43c6-b90b-1d830b958ef9' User entered 'None (1)'	System	14 Sep 2020 23:46:38
	System	14 Sep 2020 23:46:38

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:34', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '1386bfa2-da8a-43c6-b90b-1d830b958ef9' User entered '14 Sep 2020 18:46'	System	14 Sep 2020 23:46:38
	System	14 Sep 2020 23:46:38

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:26', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e' User entered 'None (0)'	System	08 Sep 2020 17:09:49
	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:28', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e' User entered 'None (0)'	System	08 Sep 2020 17:09:49
	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:30', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e' User entered 'None (0)'	System	08 Sep 2020 17:09:49
	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:32', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e' User entered 'None (0)'	System	08 Sep 2020 17:09:49
	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:38', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e' User entered 'None (0)'	System	08 Sep 2020 17:09:49
	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:40', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e' User entered 'None (0)'	System	08 Sep 2020 17:09:49
	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:44', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e' User entered 'No (N)'	System	08 Sep 2020 17:09:49
	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T12:09:47', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5965d6c-923a-49ae-84c0-92901daa535e' User entered '08 Sep 2020 12:09'	System	08 Sep 2020 17:09:49
	System	08 Sep 2020 17:09:49

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '08 Sep 2020 11:53'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '08 Sep 2020 14:23'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:26:20', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a' User entered 'None (0)'	System	09 Sep 2020 01:27:16
	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:26:37', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a' User entered 'None (0)'	System	09 Sep 2020 01:27:16
	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:26:40', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a' User entered 'None (0)'	System	09 Sep 2020 01:27:16
	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:26:54', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a' User entered 'None (0)'	System	09 Sep 2020 01:27:16
	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:26:57', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a' User entered 'None (0)'	System	09 Sep 2020 01:27:16
	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:26:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a' User entered 'None (0)'	System	09 Sep 2020 01:27:16
	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:27:10', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a' User entered 'No (N)'	System	09 Sep 2020 01:27:16
	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-08T20:27:13', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'dbe082dc-4612-482c-99c7-5bba8c08c89a' User entered '08 Sep 2020 20:27'	System	09 Sep 2020 01:27:16
	System	09 Sep 2020 01:27:16

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '08 Sep 2020 15:18'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 2'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:22', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7' User entered 'None (0)'	System	09 Sep 2020 21:03:45
	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:26', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7' User entered 'None (0)'	System	09 Sep 2020 21:03:45
	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:28', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7' User entered 'None (0)'	System	09 Sep 2020 21:03:45
	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:31', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7' User entered 'None (0)'	System	09 Sep 2020 21:03:45
	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:33', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7' User entered 'None (0)'	System	09 Sep 2020 21:03:45
	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:35', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7' User entered 'None (0)'	System	09 Sep 2020 21:03:45
	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:38', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7' User entered 'No (N)'	System	09 Sep 2020 21:03:45
	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-09T16:03:40', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5f182721-613d-4f8b-abfe-fdb47e927db7' User entered '09 Sep 2020 16:03'	System	09 Sep 2020 21:03:45
	System	09 Sep 2020 21:03:45

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 3'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:03', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801'	System	11 Sep 2020 04:41:33
User entered 'No interference with activity (1)'	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:08', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801' User entered 'None (0)'	System	11 Sep 2020 04:41:33
	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:11', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801' User entered 'None (0)'	System	11 Sep 2020 04:41:33
	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:15', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801' User entered 'None (0)'	System	11 Sep 2020 04:41:33
	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:18', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801' User entered 'None (0)'	System	11 Sep 2020 04:41:33
	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:20', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801' User entered 'None (0)'	System	11 Sep 2020 04:41:33
	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:26', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801' User entered 'No (N)'	System	11 Sep 2020 04:41:33
	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-10T23:41:31', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '36f8dee7-e193-45de-8aa9-5603527dd801' User entered '10 Sep 2020 23:41'	System	11 Sep 2020 04:41:33
	System	11 Sep 2020 04:41:33

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 4'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:11', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f' User entered 'None (0)'	System	11 Sep 2020 20:26:29
	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f' User entered 'None (0)'	System	11 Sep 2020 20:26:29
	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:15', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f' User entered 'None (0)'	System	11 Sep 2020 20:26:29
	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:17', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f' User entered 'None (0)'	System	11 Sep 2020 20:26:29
	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f' User entered 'None (0)'	System	11 Sep 2020 20:26:29
	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:21', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f' User entered 'None (0)'	System	11 Sep 2020 20:26:29
	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:25', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f' User entered 'No (N)'	System	11 Sep 2020 20:26:29
	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-11T15:26:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'eefae5ba-e814-42c1-a474-e14534206e9f' User entered '11 Sep 2020 15:26'	System	11 Sep 2020 20:26:29
	System	11 Sep 2020 20:26:29

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 5'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:25', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c' User entered 'None (0)'	System	12 Sep 2020 17:12:43
	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:28', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c' User entered 'None (0)'	System	12 Sep 2020 17:12:43
	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:30', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c' User entered 'None (0)'	System	12 Sep 2020 17:12:43
	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:32', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c' User entered 'None (0)'	System	12 Sep 2020 17:12:43
	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:34', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c' User entered 'None (0)'	System	12 Sep 2020 17:12:43
	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:36', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c' User entered 'None (0)'	System	12 Sep 2020 17:12:43
	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:39', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c' User entered 'No (N)'	System	12 Sep 2020 17:12:43
	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-12T12:12:41', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '70cb87ba-eb0f-4511-b068-7406dd17808c' User entered '12 Sep 2020 12:12'	System	12 Sep 2020 17:12:43
	System	12 Sep 2020 17:12:43

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 6'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:56', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65' User entered 'None (0)'	System	13 Sep 2020 17:02:59
	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:01:58', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65' User entered 'None (0)'	System	13 Sep 2020 17:02:59
	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:02:01', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65' User entered 'None (0)'	System	13 Sep 2020 17:02:59
	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:02:03', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65' User entered 'None (0)'	System	13 Sep 2020 17:02:59
	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:02:05', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65' User entered 'None (0)'	System	13 Sep 2020 17:02:59
	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:02:07', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65' User entered 'None (0)'	System	13 Sep 2020 17:02:59
	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:02:16', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65' User entered 'No (N)'	System	13 Sep 2020 17:02:59
	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-13T12:02:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '90b13962-a3f4-45df-b424-244dfdbbcd65' User entered '13 Sep 2020 12:02'	System	13 Sep 2020 17:02:59
	System	13 Sep 2020 17:02:59

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	08 Sep 2020 16:42:30
User entered 'Day 7'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:38', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247' User entered 'None (0)'	System	14 Sep 2020 23:46:54
	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:39', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247' User entered 'None (0)'	System	14 Sep 2020 23:46:54
	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:41', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247' User entered 'None (0)'	System	14 Sep 2020 23:46:54
	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:43', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247' User entered 'None (0)'	System	14 Sep 2020 23:46:54
	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:45', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247' User entered 'None (0)'	System	14 Sep 2020 23:46:54
	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:47', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247' User entered 'None (0)'	System	14 Sep 2020 23:46:54
	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:49', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247' User entered 'No (N)'	System	14 Sep 2020 23:46:54
	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-09-14T18:46:52', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'f40534eb-6e17-465b-826b-a1d7790a9247' User entered '14 Sep 2020 18:46'	System	14 Sep 2020 23:46:54
	System	14 Sep 2020 23:46:54

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:42:30

US3272026

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:18:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:42:30

US3272026

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:22:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 15:44:52

US3272026

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:22:44
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 15:44:52

US3272026

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:22:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Sep 2020 15:44:52

US3272026

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:22:44
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 15:44:52

US3272026

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:22:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 15:44:54

US3272026

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:45:09
User entered 'I'	System	15 Sep 2020 15:44:54

US3272026

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:23:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 15:50:11

US3272026

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:23:22
User entered '22 Sep 2020'		22 Sep 2020 15:50:11

US3272026

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:23:22
User entered 'Contact Made (CONTACT MADE)'		22 Sep 2020 15:50:11

US3272026

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:23:22
User entered empty.		22 Sep 2020 15:50:11

US3272026

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:23:30
User entered 'Yes (Y)'		22 Sep 2020 15:50:14

US3272026

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:22:52
User entered 'I'	System	22 Sep 2020 15:50:14

US3272026

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:23:43
User entered 'Yes (Y)'		09 Oct 2020 18:38:18

US3272026

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:23:43
User entered '29 Sep 2020'		09 Oct 2020 18:38:18

US3272026

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:23:43
User entered 'Contact Made (CONTACT MADE)'		09 Oct 2020 18:38:18

US3272026

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:23:43
User entered empty.		09 Oct 2020 18:38:18

US3272026

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:23:47
User entered 'Yes (Y)'		09 Oct 2020 18:38:24

US3272026

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:43:52
User entered 'I'	System	09 Oct 2020 18:38:24

US3272026

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:23:59
User entered 'Yes (Y)'		09 Oct 2020 18:38:42

US3272026

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:23:59
User entered '9 Oct 2020'		09 Oct 2020 18:38:42

US3272026

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:23:59
User entered 'Clinic (Clinic)'		09 Oct 2020 18:38:42

US3272026

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered 'VISIT3'	System	09 Oct 2020 18:38:42

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:20
User entered 'Yes (Y)'		09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:20
User entered '9 Oct 2020'		09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:20
User entered '12:53'		09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered '9 Oct 2020 12:53'	System	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:20
User entered '37.0' C		09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:20
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:20
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:20
User entered '83'		09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered 'bpm'	System	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:20
User entered '18'		09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered 'breaths/min'	System	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:20
User entered '136'		09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered 'mmHg'	System	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:20
User entered '87'		09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered 'mmHg'	System	09 Oct 2020 18:39:32

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04

US3272026

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04

US3272026

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:27
User entered 'Yes (Y)'		09 Oct 2020 18:39:40

US3272026

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:27
User entered '9 Oct 2020'		09 Oct 2020 18:39:40

US3272026

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 18:39:55

US3272026

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:33
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 18:39:55

US3272026

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:33
User entered '13:05'		09 Oct 2020 18:39:55

US3272026

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered '9 Oct 2020 13:05'	System	09 Oct 2020 18:39:55

US3272026

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:24:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 18:39:59

US3272026

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:32:04
User entered '1'	System	09 Oct 2020 18:39:59

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 64'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-01T06:25:36', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '0427386a-ff81-4a7d-9b7d-abbe8686b45a' User entered 'No (N)'	System	01 Oct 2020 11:25:57
	System	01 Oct 2020 11:25:57

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-01T06:25:45', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '0427386a-ff81-4a7d-9b7d-abbe8686b45a' User entered 'No (N)'	System	01 Oct 2020 11:25:57
	System	01 Oct 2020 11:25:57

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-01T06:25:56', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '0427386a-ff81-4a7d-9b7d-abbe8686b45a' User entered '01 Oct 2020 06:25:56'	System	01 Oct 2020 11:25:57
	System	01 Oct 2020 11:25:57

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '01 Oct 2020 00:01'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '05 Oct 2020 23:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 71'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-08T07:53:06', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '63b3ef3e-e7ea-41ed-b4ad-2c0f7210e6d5'	System	08 Oct 2020 12:53:29
User entered 'No (N)'	System	08 Oct 2020 12:53:29

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-08T07:53:18', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '63b3ef3e-e7ea-41ed-b4ad-2c0f7210e6d5'	System	08 Oct 2020 12:53:29
User entered 'No (N)'	System	08 Oct 2020 12:53:29

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-08T07:53:24', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '63b3ef3e-e7ea-41ed-b4ad-2c0f7210e6d5' User entered '08 Oct 2020 07:53:24'	System	08 Oct 2020 12:53:29
	System	08 Oct 2020 12:53:29

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '08 Oct 2020 00:01'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '12 Oct 2020 23:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 78'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-15T10:36:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f71f590-856e-4423-b6b1-b52340361eca' User entered 'No (N)'	System	15 Oct 2020 15:37:18
	System	15 Oct 2020 15:37:18

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-15T10:37:10', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f71f590-856e-4423-b6b1-b52340361eca' User entered 'No (N)'	System	15 Oct 2020 15:37:18
	System	15 Oct 2020 15:37:18

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-15T10:37:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f71f590-856e-4423-b6b1-b52340361eca' User entered '15 Oct 2020 10:37:14'	System	15 Oct 2020 15:37:18
	System	15 Oct 2020 15:37:18

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '15 Oct 2020 00:01'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '19 Oct 2020 23:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 92'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-29T07:10:23', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9790b8c1-a722-4a85-b5bb-cc30ee7e7cc9' User entered 'No (N)'	System	29 Oct 2020 12:11:05
	System	29 Oct 2020 12:11:05

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-29T07:10:48', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9790b8c1-a722-4a85-b5bb-cc30ee7e7cc9'	System	29 Oct 2020 12:11:05
User entered 'No (N)'	System	29 Oct 2020 12:11:05

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-10-29T07:11:00', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '9790b8c1-a722-4a85-b5bb-cc30ee7e7cc9' User entered '29 Oct 2020 07:11:00'	System	29 Oct 2020 12:11:05
	System	29 Oct 2020 12:11:05

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '29 Oct 2020 00:01'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '02 Nov 2020 23:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 99'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-05T09:42:11', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ca73eb11-9aa1-4c2e-a09d-ec6ea778364e' User entered 'No (N)'	System	05 Nov 2020 15:42:36
	System	05 Nov 2020 15:42:36

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-05T09:42:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ca73eb11-9aa1-4c2e-a09d-ec6ea778364e' User entered 'No (N)'	System	05 Nov 2020 15:42:36
	System	05 Nov 2020 15:42:36

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-05T09:42:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'ca73eb11-9aa1-4c2e-a09d-ec6ea778364e' User entered '05 Nov 2020 09:42:19'	System	05 Nov 2020 15:42:36
	System	05 Nov 2020 15:42:36

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '05 Nov 2020 00:01'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '09 Nov 2020 23:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 106'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:14', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430'	System	12 Nov 2020 17:45:42
User entered 'Yes (Y)'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:25', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430'	System	12 Nov 2020 17:45:42
User entered 'Yes (Y)'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:31', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430'	System	12 Nov 2020 17:45:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:40', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430'	System	12 Nov 2020 17:45:42
User entered 'Yes (Y)'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '1'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '1'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '1'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '0'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '0'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '0'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '0'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '1'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '1'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '0'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '0'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '0'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '0'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '0'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '0'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '0'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:44:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '0'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:45:05', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430'	System	12 Nov 2020 17:45:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:45:16', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430'	System	12 Nov 2020 17:45:42
User entered 'Yes (Y)'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:45:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430'	System	12 Nov 2020 17:45:42
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-12T11:45:31', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'b2ae44cf-0493-477d-bfe5-ffe32451430' User entered '12 Nov 2020 11:45:31'	System	12 Nov 2020 17:45:42
	System	12 Nov 2020 17:45:42

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '12 Nov 2020 00:01'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:26:33
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '16 Nov 2020 23:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24
Data entry locked.	System	01 Aug 2020 15:17:46
User entered 'Day 113'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '19 Nov 2020 00:01'	System	01 Aug 2020 15:17:46

US3272026

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:18:24
Data entry locked.	System	01 Aug 2020 15:17:46
User entered '23 Nov 2020 23:59'	System	01 Aug 2020 15:17:46

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:06', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered 'Yes (Y)'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:10', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered 'Yes (Y)'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:13', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:17', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered 'Yes (Y)'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '1'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '1'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '1'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '1'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '1'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '1'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '1'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '0'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:31', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:35', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered 'Yes (Y)'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:39', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3'	System	19 Nov 2020 14:40:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2020-11-19T08:40:43', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '98a510a2-83bd-408c-b1b4-c2c93864ffe3' User entered '19 Nov 2020 08:40:43'	System	19 Nov 2020 14:40:53
	System	19 Nov 2020 14:40:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-18T08:21:11', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a4cfb34a-a892-4e8a-964c-bd808db3e828' User entered 'Yes (Y)'	System	18 Jan 2021 14:21:49
	System	18 Jan 2021 14:21:49

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-18T08:21:15', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a4cfb34a-a892-4e8a-964c-bd808db3e828'	System	18 Jan 2021 14:21:49
User entered 'Yes (Y)'	System	18 Jan 2021 14:21:49

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-18T08:21:19', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a4cfb34a-a892-4e8a-964c-bd808db3e828'	System	18 Jan 2021 14:21:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Jan 2021 14:21:49

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-18T08:21:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a4cfb34a-a892-4e8a-964c-bd808db3e828' User entered 'No (N)'	System	18 Jan 2021 14:21:49

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-18T08:21:32', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a4cfb34a-a892-4e8a-964c-bd808db3e828'	System	18 Jan 2021 14:21:49
User entered 'Yes (Y)'	System	18 Jan 2021 14:21:49

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-18T08:21:34', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a4cfb34a-a892-4e8a-964c-bd808db3e828'	System	18 Jan 2021 14:21:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Jan 2021 14:21:49

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-18T08:21:38', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a4cfb34a-a892-4e8a-964c-bd808db3e828' User entered '18 Jan 2021 08:21:38'	System	18 Jan 2021 14:21:49
	System	18 Jan 2021 14:21:49

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:21', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0'	System	29 Jan 2021 00:02:01
User entered 'Yes (Y)'	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:24', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0'	System	29 Jan 2021 00:02:01
User entered 'Yes (Y)'	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0'	System	29 Jan 2021 00:02:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:31', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0'	System	29 Jan 2021 00:02:01
User entered 'Yes (Y)'	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '0'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '1'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '1'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '1'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '1'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '1'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '1'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '1'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '0'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '0'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '0'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '0'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '1'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '0'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '0'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '0'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:50', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '0'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:00:55', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0'	System	29 Jan 2021 00:02:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:01:01', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0'	System	29 Jan 2021 00:02:01
User entered 'Yes (Y)'	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:01:04', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0'	System	29 Jan 2021 00:02:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-01-28T18:01:07', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '76337d33-7127-47c1-aec6-3c2ef092e8e0' User entered '28 Jan 2021 18:01:07'	System	29 Jan 2021 00:02:01
	System	29 Jan 2021 00:02:01

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:07', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered 'Yes (Y)'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:10', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered 'Yes (Y)'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:12', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c'	System	01 Feb 2021 20:38:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:15', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered 'Yes (Y)'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '1'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '1'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '1'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '1'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '1'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '0'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '0'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '0'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '0'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '0'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '0'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '0'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '0'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '0'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '0'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '0'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '0'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:32', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c'	System	01 Feb 2021 20:38:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:35', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered 'Yes (Y)'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Please 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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:38', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c'	System	01 Feb 2021 20:38:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-01T14:37:41', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '3f854976-b680-4555-8eba-575b5d87a12c' User entered '01 Feb 2021 14:37:41'	System	01 Feb 2021 20:38:18
	System	01 Feb 2021 20:38:18

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-08T07:46:44', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5589753c-81bd-442d-954b-4135e3c66835'	System	08 Feb 2021 13:47:04
User entered 'No (N)'	System	08 Feb 2021 13:47:04

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-08T07:46:52', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5589753c-81bd-442d-954b-4135e3c66835'	System	08 Feb 2021 13:47:04
User entered 'No (N)'	System	08 Feb 2021 13:47:04

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-08T07:47:01', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '5589753c-81bd-442d-954b-4135e3c66835' User entered '08 Feb 2021 07:47:01'	System	08 Feb 2021 13:47:04
	System	08 Feb 2021 13:47:04

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-15T09:45:42', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'e824e739-e0f1-4b27-8f0d-9c8682e50771' User entered 'No (N)'	System	15 Feb 2021 15:45:53
	System	15 Feb 2021 15:45:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-15T09:45:46', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'e824e739-e0f1-4b27-8f0d-9c8682e50771' User entered 'No (N)'	System	15 Feb 2021 15:45:53
	System	15 Feb 2021 15:45:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-15T09:45:51', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'e824e739-e0f1-4b27-8f0d-9c8682e50771' User entered '15 Feb 2021 09:45:51'	System	15 Feb 2021 15:45:53
	System	15 Feb 2021 15:45:53

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-22T10:17:54', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4e28d245-76f1-473a-8b94-10e41ed17a65' User entered 'No (N)'	System	22 Feb 2021 16:18:06
	System	22 Feb 2021 16:18:06

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-22T10:17:58', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4e28d245-76f1-473a-8b94-10e41ed17a65' User entered 'No (N)'	System	22 Feb 2021 16:18:06
	System	22 Feb 2021 16:18:06

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-02-22T10:18:01', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '4e28d245-76f1-473a-8b94-10e41ed17a65' User entered '22 Feb 2021 10:18:01'	System	22 Feb 2021 16:18:06
	System	22 Feb 2021 16:18:06

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-03T12:01:29', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '8d24d05e-365e-4dda-a686-d80d5be0738e' User entered 'No (N)'	System	03 Mar 2021 18:02:51
	System	03 Mar 2021 18:02:51

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-03T12:01:33', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '8d24d05e-365e-4dda-a686-d80d5be0738e' User entered 'No (N)'	System	03 Mar 2021 18:02:51
	System	03 Mar 2021 18:02:51

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-03T12:01:38', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '8d24d05e-365e-4dda-a686-d80d5be0738e' User entered '03 Mar 2021 12:01:38'	System	03 Mar 2021 18:02:51
	System	03 Mar 2021 18:02:51

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-09T19:04:56', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5ffb071-38dc-4fcd-ae09-3734c6a2acdf' User entered 'No (N)'	System	10 Mar 2021 01:05:14
	System	10 Mar 2021 01:05:14

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-09T19:05:02', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5ffb071-38dc-4fcd-ae09-3734c6a2acdf'	System	10 Mar 2021 01:05:14
User entered 'No (N)'	System	10 Mar 2021 01:05:14

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-09T19:05:05', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'a5ffb071-38dc-4fcd-ae09-3734c6a2acdf' User entered '09 Mar 2021 19:05:05'	System	10 Mar 2021 01:05:14
	System	10 Mar 2021 01:05:14

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-15T12:42:18', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '17f23d6c-7bd1-42ac-968f-d6304cea2fd2'	System	18 Mar 2021 00:18:07
User entered 'No (N)'	System	18 Mar 2021 00:18:07

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-15T12:42:24', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '17f23d6c-7bd1-42ac-968f-d6304cea2fd2'	System	18 Mar 2021 00:18:07
User entered 'No (N)'	System	18 Mar 2021 00:18:07

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-15T12:42:27', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '17f23d6c-7bd1-42ac-968f-d6304cea2fd2'	System	18 Mar 2021 00:18:07
User entered '15 Mar 2021 12:42:27'	System	18 Mar 2021 00:18:07

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-22T10:14:52', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '00263213-61d1-4a5a-be4f-736c4be29143' User entered 'No (N)'	System	22 Mar 2021 15:15:11
	System	22 Mar 2021 15:15:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-22T10:14:56', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '00263213-61d1-4a5a-be4f-736c4be29143' User entered 'No (N)'	System	22 Mar 2021 15:15:11
	System	22 Mar 2021 15:15:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-22T10:14:59', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '00263213-61d1-4a5a-be4f-736c4be29143' User entered '22 Mar 2021 10:14:59'	System	22 Mar 2021 15:15:11
	System	22 Mar 2021 15:15:11

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-29T12:14:22', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '92c8f4e5-cb50-42ac-a723-ce543454d700'	System	29 Mar 2021 17:14:44
User entered 'No (N)'	System	29 Mar 2021 17:14:44

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

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)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-29T12:14:26', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '92c8f4e5-cb50-42ac-a723-ce543454d700'	System	29 Mar 2021 17:14:44
User entered 'No (N)'	System	29 Mar 2021 17:14:44

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-29T12:14:41', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: '92c8f4e5-cb50-42ac-a723-ce543454d700' User entered '29 Mar 2021 12:14:41'	System	29 Mar 2021 17:14:44
	System	29 Mar 2021 17:14:44

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 11:18:24

US3272026

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:18:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:18:24
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 11:18:24

US3272026

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:18:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-03T12:01:48', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'efd98585-7903-42a3-9090-33ec1cc789b6'	System	03 Mar 2021 18:04:20
User entered 'No (N)'	System	03 Mar 2021 18:04:20

US3272026

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:18:59

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:32:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5419659-68E8-4362-8598-F11DAB09BEA4)', Time: '2021-03-03T12:01:52', User OID: 'PatientReportedOutcome (US3272026)', ODM File OID: 'efd98585-7903-42a3-9090-33ec1cc789b6' User entered '03 Mar 2021 12:01:52'	System	03 Mar 2021 18:04:20
	System	03 Mar 2021 18:04:20

US3272026

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:25:17
User entered 'Yes (Y)'		29 Mar 2021 16:53:39

US3272026

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:25:17
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Mar 2021 16:53:45
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	29 Mar 2021 16:53:45
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	29 Mar 2021 16:53:45
User entered '02 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 16:53:45
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	29 Mar 2021 16:53:39
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Mar 2021 16:53:39
User entered '02 Nov 2021'	(b) (4), (b) (6)	29 Mar 2021 16:53:39

US3272026

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:25:17
User entered 'Contact Made (CONTACT MADE)'		29 Mar 2021 16:53:39

US3272026

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:25:17
User entered empty.		29 Mar 2021 16:53:39

US3272026

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:25:21
User entered 'Yes (Y)'	Whitney West (b) (4)	02 Feb 2021 19:12:55

US3272026

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:45:03
User entered 'I'	System	02 Feb 2021 19:12:55

US3272026

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:59:51
User entered 'No (N)'		18 Mar 2021 23:19:05

US3272026

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:59:51
User entered empty.		18 Mar 2021 23:19:05

US3272026

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:59:51
User entered empty.		18 Mar 2021 23:19:05

US3272026

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:59:51
User closed query 'Please provide comment reason why Contact was not made.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 14:59:48
Query 'Please provide comment reason why Contact was not made.' answered with 'Updated. ' (Site from CRA).	Whitney West (b) (4)	14 Apr 2021 14:57:00
User entered 'Subject was intubated and sedated. Unable to communicate.' reason for change: Per Query Resolution	Whitney West (b) (4)	14 Apr 2021 14:56:41
User opened query 'Please provide comment reason why Contact was not made.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 14:26:36
User entered empty.	(b) (4), (b) (6)	18 Mar 2021 23:19:05

US3272026

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:26:44
User entered 'Yes (Y)'	Whitney West (b) (4)	02 Feb 2021 19:13:09

US3272026

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:12:39
User entered 'I'	System	02 Feb 2021 19:13:09

US3272026

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:54:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:00:06
User entered 'No (N)'		18 Mar 2021 23:19:15

US3272026

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:54:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:00:06
User entered empty.		18 Mar 2021 23:19:15

US3272026

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:54:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:00:06
User entered empty.		18 Mar 2021 23:19:15

US3272026

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:54:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:00:06
User closed query 'Please provide reason contact was not made.' (Site from CRA).	(b) (4)	14 Apr 2021 15:00:03
Query 'Please provide reason contact was not made.' answered with 'Updated. ' (Site from CRA).	Whitney West (b) (4)	14 Apr 2021 14:58:02
User entered 'Unable to communicate. Sedated and intubated.' reason for change: Data Entry Error	Whitney West (b) (4)	14 Apr 2021 14:57:56
User opened query 'Please provide reason contact was not made.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 14:27:12
User entered empty.	(b) (4), (b) (6)	18 Mar 2021 23:19:15

US3272026

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:54:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:27:18
User entered 'Yes (Y)'	Whitney West (b) (4)	02 Feb 2021 19:13:17

US3272026

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:54:18
User entered 'I'	System	02 Feb 2021 19:13:17

US3272026

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:27:25
User entered 'Yes (Y)'	Whitney West (b) (4)	02 Feb 2021 19:13:37

US3272026

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:27:25
User entered '02 Feb 2021'	Whitney West (b) (4)	02 Feb 2021 19:13:37

US3272026

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:27:25
User entered 'Contact Made (CONTACT MADE)'	Whitney West (b) (4)	02 Feb 2021 19:13:37

US3272026

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:18:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:27:25
User entered empty.	Whitney West (b) (4)	02 Feb 2021 19:13:37

US3272026

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:27:29
User entered 'No (N)' reason for change: Data Entry Error	Ashley Bell (b) (4)	31 Mar 2021 19:46:33
User entered 'Yes (Y)'	Whitney West (b) (4)	02 Feb 2021 19:13:46

US3272026

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:18:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:20:07
User entered empty.	System	31 Mar 2021 19:46:33
User entered 'I'	System	02 Feb 2021 19:13:46

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:18:59

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Please reconcile and add severity log as required. Of note 16Nov2020 subject O2 was 80% so ensure that is captured on severity page.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:59:20
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:03
Query 'Please reconcile and add severity log as required. Of note 16Nov2020 subject O2 was 80% so ensure that is captured on severity page.' answered with 'this was updated' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 14:50:30
User opened query 'Please reconcile and add severity log as required. Of note 16Nov2020 subject O2 was 80% so ensure that is captured on severity page.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:03:27
User entered '11 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 20:42:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:18:59

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:03
User entered '14:19'		12 Nov 2020 20:42:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:18:59

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:27
User entered '11 Nov 2020 14:19'	System	12 Nov 2020 20:42:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:18:59

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 15:33:58
User closed query 'Per ETRTR: "Clinic Visit -Scheduled" refers to a Protocol Scheduled visit. Since 11Nov20 does not correspond to Visit 01, 02, 03, etc. Please consider updating answer to "Clinic Visit - Unscheduled" as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 15:33:55
Query 'Per ETRTR: "Clinic Visit -Scheduled" refers to a Protocol Scheduled visit. Since 11Nov20 does not correspond to Visit 01, 02, 03, etc. Please consider updating answer to "Clinic Visit - Unscheduled" as applicable, thanks.' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4)	18 Dec 2020 21:52:04
DataPoint Un-verified.	Kayla Flege (b) (4)	18 Dec 2020 21:51:59
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Kayla Flege (b) (4)	18 Dec 2020 21:51:59
User opened query 'Per ETRTR: "Clinic Visit -Scheduled" refers to a Protocol Scheduled visit. Since 11Nov20 does not correspond to Visit 01, 02, 03, etc. Please consider updating answer to "Clinic Visit - Unscheduled" as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 17:50:35
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:03
User entered 'Clinic Visit - Scheduled (Clinic Visit Scheduled)'		12 Nov 2020 20:42:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:18:59

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 20:42:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per CDM: It appears that 'Assessment Not Done' was checked yet data is present for Day 30. Also, 'Assessment Not Done' was not checked and data was not provided for Day 29, 33, 34 & Day 35. Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:14:22
Query 'Per CDM: It appears that 'Assessment Not Done' was checked yet data is present for Day 30. Also, 'Assessment Not Done' was not checked and data was not provided for Day 29, 33, 34 & Day 35. Please review and update accordingly. Thank you. ' answered with 'assessment was not completed for that day, but information on symptoms was collected for that day' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 22:15:40
User opened query 'Per CDM: It appears that 'Assessment Not Done' was checked yet data is present for Day 30. Also, 'Assessment Not Done' was not checked and data was not provided for Day 29, 33, 34 & Day 35. Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:37:49
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '8 Nov 2020'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:44:20

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:44:20

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:44:20

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	12 Nov 2020 20:45:17

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '9 Nov 2020'		12 Nov 2020 20:45:17

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'		12 Nov 2020 20:45:17

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.		12 Nov 2020 20:45:17

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	12 Nov 2020 20:45:17

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.		12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:45:17

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:45:17

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:45:17

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:45:17

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:45:17

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:45:17

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:45:17

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 3 (Day 3)'	(b) (4), (b) (6)	12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '10 Nov 2020'		12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'		12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.		12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.		12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:46:05

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:46:05

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '11 Nov 2020'		12 Nov 2020 20:47:31

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'		12 Nov 2020 20:47:31

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.		12 Nov 2020 20:47:31

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	12 Nov 2020 20:47:31

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done.		12 Nov 2020 20:47:31

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:47:31

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:47:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '12 Nov 2020'		12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'		12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '100'		12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	12 Nov 2020 20:53:49

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '97.4' F		12 Nov 2020 20:53:49

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:53:49

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'		12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:53:49

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:53:49

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:53:49

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:53:49

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		12 Nov 2020 20:53:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '13 Nov 2020'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '97'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	14 Nov 2020 15:20:49

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '98.5' F		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'		14 Nov 2020 15:20:49

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 15:20:49

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 15:20:49

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '14 Nov 2020'		14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'		14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '97'		14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '101.5' F		14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'		14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'		14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 22:25:29

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 22:25:29

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 22:25:29

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 22:25:29

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 22:25:29

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 22:25:29

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		14 Nov 2020 22:25:29

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	15 Nov 2020 21:38:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '15 Nov 2020'		15 Nov 2020 21:38:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'		15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '96'		15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	15 Nov 2020 21:38:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '98.3' F		15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'		15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'		15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		15 Nov 2020 21:38:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		15 Nov 2020 21:38:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		15 Nov 2020 21:38:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		15 Nov 2020 21:38:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		15 Nov 2020 21:38:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		15 Nov 2020 21:38:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '16 Nov 2020'		17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'		17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '80'		17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '103.1' F		17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Severe (Severe)'		17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'		17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Severe (Severe)'		17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Severe (Severe)'		17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Severe (Severe)'		17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'		17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'		17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'		17 Nov 2020 19:42:56

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'		17 Nov 2020 19:42:56

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		17 Nov 2020 19:42:56

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		17 Nov 2020 19:42:56

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		17 Nov 2020 19:42:56

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 19:42:56

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		17 Nov 2020 19:42:56

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		17 Nov 2020 19:42:56

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 10 (Day 10)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '17 Nov 2020'		17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'		17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:57:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:57:20
User entered 'UNK' (non-conformant).	(b) (4), (b) (6)	17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	17 Nov 2020 19:57:39
User entered empty.	System	17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:57:39
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Nov 2020 19:57:20
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:57:20
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Nov 2020 19:57:01
User entered 'UNK' (non-conformant).	(b) (4), (b) (6)	17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'		17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Severe (Severe)'		17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Severe (Severe)'		17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'		17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'		17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'		17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'		17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'		17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'		17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'		17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Not Done (Not Done)'		17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		17 Nov 2020 19:57:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'		17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	(b) (4), (b) (6)	17 Nov 2020 19:57:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 11 (Day 11)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '18 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 21:55:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '0'	Whitney West (b) (4)	19 Nov 2020 21:55:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '94'	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered '100.2' F	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Moderate (Moderate)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'Mild (Mild)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:44
User entered 'None (None)'	Whitney West (b) (4)	19 Nov 2020 21:55:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	Whitney West (b) (4)	20 Nov 2020 21:41:24
User entered 'Day 19 (Day 19)'	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '19 Nov 2020'	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'I'	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:16

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 13 (Day 13)' reason for change:	Whitney West (b) (4)	20 Nov 2020 21:41:52
Data Entry Error	(b) (4)	
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 21:41:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 21:41:52
User entered '20 Nov 2020' reason for change: Data Entry Error	Whitney West (b) (4)	20 Nov 2020 21:41:52
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 21:41:24
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '1' reason for change: Data Entry Error	Whitney West (b) (4)	20 Nov 2020 21:41:52
User entered '0'	Whitney West (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered empty.	Whitney West (b) (4)	20 Nov 2020 21:41:24

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 14 (Day 14)'	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User closed query 'Please reconcile and enter all missing fields. If not completed please mark each field as ND - Not Done' (Site from CRA).		24 Nov 2020 03:20:24
Query 'Please reconcile and enter all missing fields. If not completed please mark each field as ND - Not Done' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4)	23 Nov 2020 22:21:46
User opened query 'Please reconcile and enter all missing fields. If not completed please mark each field as ND - Not Done' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:33:59
User entered '21 Nov 2020'	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '0'		21 Nov 2020 16:00:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '90'		21 Nov 2020 16:00:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Nov 2020 16:01:59
User entered '98' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Nov 2020 16:01:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Nov 2020 16:00:57
User entered '98' (non-conformant).	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:21:42
User entered empty.	(b) (4), (b) (6)	21 Nov 2020 16:00:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 15 (Day 15)'	Kayla Flege (b) (4)	22 Nov 2020 18:21:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '22 Nov 2020'	Kayla Flege (b) (4)	22 Nov 2020 18:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '0'	Kayla Flege (b) (4)	22 Nov 2020 18:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '90'	Kayla Flege (b) (4)	22 Nov 2020 18:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	22 Nov 2020 18:21:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '98.9' F	Kayla Flege (b) (4)	22 Nov 2020 18:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4)	22 Nov 2020 18:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Moderate (Moderate)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Moderate (Moderate)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Moderate (Moderate)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)'	Kayla Flege (b) (4) (b) (4)	22 Nov 2020 18:21:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4)	22 Nov 2020 18:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4)	22 Nov 2020 18:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4)	22 Nov 2020 18:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4)	22 Nov 2020 18:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4)	22 Nov 2020 18:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4)	22 Nov 2020 18:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4)	22 Nov 2020 18:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Kayla Flege (b) (4)	22 Nov 2020 18:21:42
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 16 (Day 16)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '23 Nov 2020'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '0'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '68'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered '98.3' F	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:19:23
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	23 Nov 2020 23:41:50

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 17 (Day 17)'	Andrea Clement (b) (4)	25 Nov 2020 22:17:23

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:44:16
User entered '24 Nov 2020'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:44:18
User entered '0'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:44:24
User entered '90'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	25 Nov 2020 22:17:23

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:44:48
User entered '99.3' F	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:46:13
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:46:25
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:47:03
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

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Folder: Covid-19 Assessment 11 Nov 2020

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:47:05
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:47:13
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:47:15
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:47:24
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:47:27
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:47:29
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:47:31
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:47:33
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:47:36
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:47:40
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:47:42
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:47:44
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:47:47
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:17:23

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 18 (Day 18)'	Andrea Clement (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:48:56
User entered '25 Nov 2020'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:48:59
User entered '0'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:49:23
User entered '81'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:49:25
User entered '98.2' F	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:49:33
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:49:36
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:49:40
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:49:47
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:53:55
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:53:59
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:54:02
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:54:05
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:54:09
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:54:19
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:54:21
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:54:24
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:54:27
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:54:30
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:54:36
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:54:38
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	25 Nov 2020 22:19:27

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 19 (Day 19)'	Andrea Clement (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:57:31
User entered '26 Nov 2020'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:57:29
User entered '0'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:57:24
User entered '64'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:57:26
User entered '98.3' F	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:57:53
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:57:56
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:58:02
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:58:06
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 19:56:12
User closed query 'please verify as moderate as per source' (Site from CRA).	(b) (4)	18 Mar 2021 19:56:09
Query 'please verify as moderate as per source' answered with 'Fixed typo. Thank you!' (Site from CRA).	Whitney West (b) (4)	27 Feb 2021 20:35:39
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	27 Feb 2021 20:35:29
User opened query 'please verify as moderate as per source' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 19:58:45
User entered 'Severe (Severe)'	Andrea Clement (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:59:23
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:59:25
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:59:28
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:59:31
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:59:33
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:59:36
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:59:40
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:59:42
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:59:46
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:59:49
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:59:52
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 20 (Day 20)'	Andrea Clement (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:00:23
User entered '27 Nov 2020'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:00:30
User entered '0'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:00:34
User entered '77'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:00:37
User entered '97.2' F	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:00:40
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:00:43
User entered 'Moderate (Moderate)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:00:46
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:00:49
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:00:52
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:00:57
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:01:02
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:01:05
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:01:07
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:01:12
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:01:17
User entered 'Mild (Mild)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:01:20
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:01:26
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:01:28
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:01:31
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:01:33
User entered 'None (None)'	Andrea Clement (b) (4) (b) (4)	27 Nov 2020 20:55:11

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 21 (Day 21)'	Andrea Clement (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:02:03
User entered '28 Nov 2020'	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:02:08
User entered 'I'	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:02:10
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:02:12
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:02:14
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:02:16
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:02:19
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:02:23
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:02:25
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:02:27
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:02:29
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:02:30
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:02:33
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:02:34
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:02:47
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:04:58
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:05:00
User entered empty.	Andrea Clement (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:05:02
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:05:07
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:05:10
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 22 (Day 22)'	Andrea Clement (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:05:53
User entered '29 Nov 2020'	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:05:55
User entered 'I'	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:06:22
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:06:27
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:06:29
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:06:31
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:06:33
User entered empty.	Andrea Clement (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:06:35
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:06:40
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:06:45
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:06:48
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:06:50
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:06:56
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:06:54
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:08:36
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:08:38
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:08:41
User entered empty.	Andrea Clement (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:08:43
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:08:47
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:08:50
User entered empty.	Andrea Clement (b) (4) (b) (4)	29 Nov 2020 21:14:33

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 23 (Day 23)'	(b) (4), (b) (6)	01 Dec 2020 16:15:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:09:15
User entered '30 Nov 2020'		01 Dec 2020 16:15:31

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:09:35
User entered 'l'		01 Dec 2020 16:15:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:09:38
User entered empty.		01 Dec 2020 16:15:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	01 Dec 2020 16:15:31

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:09:43
User entered empty.		01 Dec 2020 16:15:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:09:45
User entered empty.		01 Dec 2020 16:15:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:09:48
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 16:15:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:09:50
User entered empty.		01 Dec 2020 16:15:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:09:52
User entered empty.		01 Dec 2020 16:15:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:09:55
User entered empty.		01 Dec 2020 16:15:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:09:59
User entered empty.		01 Dec 2020 16:15:31

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:10:01
User entered empty.		01 Dec 2020 16:15:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:10:04
User entered empty.		01 Dec 2020 16:15:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:10:06
User entered empty.		01 Dec 2020 16:15:31

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:10:09
User entered empty.		01 Dec 2020 16:15:31

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:10:11
User entered empty.		01 Dec 2020 16:15:31

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:10:13
User entered empty.		01 Dec 2020 16:15:31

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:10:17
User entered empty.		01 Dec 2020 16:15:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:10:19
User entered empty.		01 Dec 2020 16:15:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:10:21
User entered empty.		01 Dec 2020 16:15:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:10:23
User entered empty.		01 Dec 2020 16:15:31

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 24 (Day 24)'	(b) (4), (b) (6)	01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:11:41
User entered '01 Dec 2020'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:11:43
User entered '0'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:11:48
User entered '94'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:11:52
User entered '97.4' F		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:12:37
User entered 'None (None)'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:12:41
User entered 'Mild (Mild)'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:12:48
User entered 'Moderate (Moderate)'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:12:51
User entered 'Moderate (Moderate)'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:12:56
User entered 'Mild (Mild)'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:12:59
User entered 'Mild (Mild)'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:13:03
User entered 'Mild (Mild)'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:13:09
User entered 'Not Done (Not Done)'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:13:12
User entered 'Not Done (Not Done)'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:13:14
User entered 'Not Done (Not Done)'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:13:16
User entered 'Not Done (Not Done)'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:13:18
User entered 'Not Done (Not Done)'		01 Dec 2020 17:44:41

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:13:20
User entered 'Not Done (Not Done)'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:13:23
User entered 'Not Done (Not Done)'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:13:27
User entered 'Not Done (Not Done)'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:13:29
User entered 'Not Done (Not Done)'		01 Dec 2020 17:44:41

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 25 (Day 25)'	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:15:43
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Dec 2020 00:30:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Dec 2020 00:30:34
User entered '02 Dec 2020' reason for change: Data Entry Error	Whitney West (b) (4)	06 Dec 2020 00:30:34
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Dec 2020 00:30:02
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:15:47
User entered '1' reason for change: Data Entry Error	Whitney West (b) (4)	06 Dec 2020 00:30:34
User entered '0'	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:15:49
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:15:51
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:15:53
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:15:58
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:16:00
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:16:02
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:16:04
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:16:06
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:16:08
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:16:10
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:16:15
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:16:17
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:16:19
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:16:21
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:16:24
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:16:26
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:16:28
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:16:30
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:02

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 26 (Day 26)'	Whitney West (b) (4)	06 Dec 2020 00:30:34

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:17:36
User entered '03 Dec 2020'	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:17:38
User entered 'l'	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:18:24
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:18:26
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:18:28
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:18:30
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:18:32
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:18:39
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:18:41
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:18:43
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:18:46
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:18:48
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:18:52
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:18:54
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:18:56
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:18:58
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:00
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:02
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:05
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:08
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:34

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 27 (Day 27)'	Whitney West (b) (4)	06 Dec 2020 00:30:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:16
User entered '04 Dec 2020'	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:18
User entered 'I'	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:22
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:24
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:26
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:28
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:30
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:34
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:36
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:38
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:41
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:42
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:45
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:47
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:49
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:55
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:52
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:57
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:19:59
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:20:02
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:30:57

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 28 (Day 28)'	Whitney West (b) (4)	06 Dec 2020 00:32:06

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:20:10
User entered '05 Dec 2020'	Whitney West (b) (4)	06 Dec 2020 00:32:06

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:20:13
User entered 'I'	Whitney West (b) (4)	06 Dec 2020 00:32:06

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:20:49
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:20:52
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:20:54
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:20:57
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:20:59
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:21:01
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:21:03
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:21:06
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:21:08
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:21:11
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:21:13
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:21:15
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:21:18
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:21:21
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:21:25
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:21:27
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:21:30
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:21:32
User entered empty.	Whitney West (b) (4)	06 Dec 2020 00:32:06

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 29 (Day 29)'	Andrea Clement (b) (4)	06 Dec 2020 18:39:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:18
User entered '6 Dec 2020'	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:20
User closed query 'Per CDM: 'Please update data for symptoms listed below or, select 'Assessment Not Done' if no assessment was done for ALL symptoms. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 13:39:18
Query 'Per CDM: 'Please update data for symptoms listed below or, select 'Assessment Not Done' if no assessment was done for ALL symptoms. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 14:47:04
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 14:46:49
User opened query 'Per CDM: 'Please update data for symptoms listed below or, select 'Assessment Not Done' if no assessment was done for ALL symptoms. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:25:25
User entered '0'	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:23
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	06 Dec 2020 18:39:42

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:25
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:31
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:33
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:35
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:37
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:39
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:41
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:43
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:45
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:50
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:52
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:54
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:56
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:22:58
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:00
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:02
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:05
User entered empty.	Andrea Clement (b) (4) (b) (4)	06 Dec 2020 18:39:42

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 30 (Day 30)'	Whitney West (b) (4)	08 Dec 2020 22:32:45

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:15
User entered '07 Dec 2020'	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:17
User closed query 'Per CDM: Response noted however, 'Assessment Not Done' check box should only be "selected" if no assessment is done for ALL symptoms listed. Please review/update accordingly. Thank you.' (Site from DM).		14 Jan 2021 13:39:27
Query 'Per CDM: Response noted however, 'Assessment Not Done' check box should only be "selected" if no assessment is done for ALL symptoms listed. Please review/update accordingly. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 14:48:04
User opened query 'Per CDM: Response noted however, 'Assessment Not Done' check box should only be "selected" if no assessment is done for ALL symptoms listed. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:14:00
User entered 'I'	Whitney West (b) (4)	08 Dec 2020 22:32:45

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:22
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 14:47:41
User entered '90'	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	13 Jan 2021 14:47:41
User entered '%'	System	08 Dec 2020 22:32:45

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:24
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:26
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:27
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:29
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:32
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:34
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:36
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:38
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:40
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:42
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:45
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:47
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:49
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:51
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:53
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:55
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:23:57
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:32:45

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 31 (Day 31)'	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:07
User entered '08 Dec 2020'	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:10
User entered 'I'	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:15
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:17
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:20
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:22
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:25
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:27
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:31
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:34
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:36
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:39
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:41
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:45
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:48
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:50
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:52
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:55
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:57
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:24:59
User entered empty.	Whitney West (b) (4)	08 Dec 2020 22:33:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 32 (Day 32)'	Whitney West (b) (4)	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:25:08
User entered '09 Dec 2020'	Whitney West (b) (4)	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:25:11
User entered 'I'	Whitney West (b) (4)	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:25:14
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:25:16
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:25:19
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:25:21
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:25:25
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:25:27
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:25:29
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:25:32
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:25:36
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:25:42
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:25:44
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:25:48
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:25:50
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:26:02
DataPoint Un-verified.		22 Feb 2021 20:25:56
DataPoint Verified.		22 Feb 2021 20:25:53
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:26:05
DataPoint Un-verified.		22 Feb 2021 20:26:00
DataPoint Verified.		22 Feb 2021 20:25:58
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:26:07
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:26:12
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:26:14
User entered empty.	Whitney West (b) (4)	09 Dec 2020 22:37:13

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 33 (Day 33)'	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:26:24
User entered '15 Dec 2020'	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:26:26
User closed query 'Per CDM: 'Please update data for symptoms listed below or, select 'Assessment Not Done' if no assessment was done for ALL symptoms. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 17:52:41
Query 'Per CDM: 'Please update data for symptoms listed below or, select 'Assessment Not Done' if no assessment was done for ALL symptoms. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 14:46:34
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 14:46:20
User opened query 'Per CDM: 'Please update data for symptoms listed below or, select 'Assessment Not Done' if no assessment was done for ALL symptoms. Thank you.' (Site from DM).		08 Jan 2021 09:26:22
User entered '0'	Whitney West (b) (4) (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:26:31
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:26:33
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:26:36
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:26:38
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:26:43
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:26:45
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:26:52
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:26:55
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:27:00
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:27:02
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:27:05
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:27:11
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:27:08
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:27:13
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:27:15
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:27:18
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:27:20
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 20:27:22
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 34 (Day 34)'	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered '22 Dec 2020'	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User closed query 'Per CDM: 'Please update data for symptoms listed below or, select 'Assessment Not Done' if no assessment was done for ALL symptoms. Thank you.' (Site from DM).		14 Jan 2021 17:52:48
Query 'Per CDM: 'Please update data for symptoms listed below or, select 'Assessment Not Done' if no assessment was done for ALL symptoms. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 14:48:20
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 14:47:30
User opened query 'Per CDM: 'Please update data for symptoms listed below or, select 'Assessment Not Done' if no assessment was done for ALL symptoms. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:26:32
User entered '0'	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:09:44

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 35 (Day 35)'	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered '28 Dec 2020'	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User closed query 'Per CDM: 'Please update data for symptoms listed below or, select 'Assessment Not Done' if no assessment was done for ALL symptoms. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 17:52:55
Query 'Per CDM: 'Please update data for symptoms listed below or, select 'Assessment Not Done' if no assessment was done for ALL symptoms. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 14:48:36
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 14:47:30
User opened query 'Per CDM: 'Please update data for symptoms listed below or, select 'Assessment Not Done' if no assessment was done for ALL symptoms. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:26:46
User entered '0'	Whitney West (b) (4) (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (35)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	05 Jan 2021 17:10:10

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 36 (Day 36)'	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered '5 Jan 2021'	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User closed query 'Per CDM: 'Assessment Not Done' check box should only be "selected" if no assessment is done for ALL symptoms listed. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 17:53:04
Query 'Per CDM: 'Assessment Not Done' check box should only be "selected" if no assessment is done for ALL symptoms listed. Please review/update accordingly. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 14:48:46
User opened query 'Per CDM: 'Assessment Not Done' check box should only be "selected" if no assessment is done for ALL symptoms listed. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:15:38
User entered 'I'	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 14:47:30
User entered missing code ND - Not Done.	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered empty.	System	13 Jan 2021 14:47:30
User entered '%'	System	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Jan 2021 14:47:30
User entered missing code ND - Not Done.	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (36)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	07 Jan 2021 23:09:40

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 37 (Day 37)'	Whitney West (b) (4)	20 Jan 2021 00:33:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered '12 Jan 2021'	Whitney West (b) (4)	20 Jan 2021 00:33:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'I'	Whitney West (b) (4)	20 Jan 2021 00:33:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered missing code ND - Not Done.	Whitney West (b) (4)	20 Jan 2021 00:33:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	20 Jan 2021 00:33:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered missing code ND - Not Done.	Whitney West (b) (4)	20 Jan 2021 00:33:52

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (37)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:33:52

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Day 38 (Day 38)'	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered '19 Jan 2021'	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'I'	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered missing code ND - Not Done.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered missing code ND - Not Done.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (38)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered empty.	Whitney West (b) (4)	20 Jan 2021 00:34:15

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per CDM: DAY has not been recorded for log line ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 15:29:35
Query 'Per CDM: DAY has not been recorded for log line ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 19:46:38
User entered 'Day 39 (Day 39)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 19:46:22
User opened query 'Per CDM: DAY has not been recorded for log line ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 06:59:24
User entered empty.	Whitney West (b) (4)	15 Feb 2021 16:26:21

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered '12 Feb 2021'	Whitney West (b) (4)	15 Feb 2021 16:26:21

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered '0'	Whitney West (b) (4)	15 Feb 2021 16:26:21

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered missing code ND - Not Done.	Whitney West (b) (4)	15 Feb 2021 16:26:21

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	15 Feb 2021 16:26:21

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered missing code ND - Not Done.	Whitney West (b) (4)	15 Feb 2021 16:26:21

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (39)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:26:21

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per CDM: DAY has not been recorded for log line ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 15:29:41
Query 'Per CDM: DAY has not been recorded for log line ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 19:47:30
User entered 'Day 40 (Day 40)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 19:47:09
User opened query 'Per CDM: DAY has not been recorded for log line ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 06:59:30
User entered empty.	Whitney West (b) (4) (b) (4)	15 Feb 2021 16:27:12

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered '10 Feb 2021'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered '0'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered missing code ND - Not Done.	Whitney West (b) (4)	15 Feb 2021 16:27:12

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User entered '%'	System	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered missing code ND - Not Done.	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (40)

Generated On: 09 Jun 2021 16:18:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:34:30
User entered 'None (None)'	Whitney West (b) (4)	15 Feb 2021 16:27:12

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:59

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:02:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:59

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered 'Yes (Y)'		12 Nov 2020 21:02:02

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:59

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 13:33:59
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'subject is positive' (Site from System).		20 Nov 2020 14:50:17
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	17 Nov 2020 19:44:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:44:44
User entered 'No (N)'		12 Nov 2020 21:02:02

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Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:59

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered '12 Nov 2020'		12 Nov 2020 21:02:02

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Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:59

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'		12 Nov 2020 21:02:02

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Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:18:59

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered empty.		12 Nov 2020 21:02:02

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Form: COVID Diagnostic Test

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[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)	30 Apr 2021 18:37:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered 'No (N)'		12 Nov 2020 21:02:02

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered empty.		12 Nov 2020 21:02:02

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Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

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[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:43:56
User entered empty.		12 Nov 2020 21:02:02

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Form: COVID Diagnostic Test

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[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:46
User entered '1'	System	17 Nov 2020 19:44:44
User entered '0'	System	12 Nov 2020 21:02:02

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:08:36
User entered '17 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:08:36
User entered '17 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:08:36
User entered '28'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

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Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:18
User entered 'Yes (Y)' reason for change: Per Query Resolution	Whitney West (b) (4)	13 Apr 2021 13:45:07
DataPoint Un-verified.	Whitney West (b) (4)	06 Dec 2020 00:40:18
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	06 Dec 2020 00:40:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per CDM: Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level? is No however the start date is present. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 14:28:28
Query 'Per CDM: Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level? is No however the start date is present. Please reconcile.' answered with 'Updated.' (Site from DM).	Whitney West (b) (4)	13 Apr 2021 13:45:31
User opened query 'Per CDM: Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level? is No however the start date is present. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 19:34:45
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per CDM : Please note the end date of Oxygen saturation is Blank. Kindly reconcile with the symptom and update accordingly. Thanks' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 07:53:21
Query 'Per CDM : Please note the end date of Oxygen saturation is Blank. Kindly reconcile with the symptom and update accordingly. Thanks' answered with 'Last known in source was patient was not transitioning off oxygen from hospitalization. End date unknown ' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 18:52:48
User opened query 'Per CDM : Please note the end date of Oxygen saturation is Blank. Kindly reconcile with the symptom and update accordingly. Thanks' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 11:36:37
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:51:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per CDM : Please note as per the symptom log the lowest oxygen level recorded is 64%, kindly update the oxygen saturation accordingly or else clarify' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 15:52:39
Query 'Per CDM : Please note as per the symptom log the lowest oxygen level recorded is 64%, kindly update the oxygen saturation accordingly or else clarify' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 21:17:10
DataPoint Un-verified.	(b) (4), (b) (6)	22 Apr 2021 21:16:34
User entered '64' reason for change: New Information	(b) (4), (b) (6)	22 Apr 2021 21:16:34
User opened query 'Per CDM : Please note as per the symptom log the lowest oxygen level recorded is 64%, kindly update the oxygen saturation accordingly or else clarify' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 11:36:20
User closed query 'Per CDM: Did the subject have Oxygen Saturation of $SpO_2 \leq 93\%$ on room air at sea level? is No however the oxygen saturation is present. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 14:27:18
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:35:16
Query 'Per CDM: Did the subject have Oxygen Saturation of $SpO_2 \leq 93\%$ on room air at sea level? is No however the oxygen saturation is present. Please reconcile. ' answered with 'Updated.' (Site from DM).	Whitney West (b) (4)	13 Apr 2021 13:46:03
User opened query 'Per CDM: Did the subject have Oxygen Saturation of $SpO_2 \leq 93\%$ on room air at sea level? is No however the oxygen saturation is present. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 19:35:23
DataPoint Un-verified.	Andrea Clement (b) (4)	23 Nov 2020 23:44:59
User entered '68' reason for change: New Information	Andrea Clement (b) (4)	23 Nov 2020 23:44:59
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
User entered '78'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:07:04

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:18
DataPoint Un-verified.	Whitney West (b) (4)	08 Dec 2020 22:34:25
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	08 Dec 2020 22:34:25
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per CDM: Non-Invasive Ventilation?' is No however the start date is present. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 14:29:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:18
Query 'Per CDM: Non-Invasive Ventilation?' is No however the start date is present. Please reconcile. ' answered with 'Updated.' (Site from DM).	Whitney West (b) (4)	13 Apr 2021 13:46:22
DataPoint Un-verified.	Whitney West (b) (4)	13 Apr 2021 13:45:07
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	13 Apr 2021 13:45:07
User opened query 'Per CDM: Non-Invasive Ventilation?' is No however the start date is present. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 19:36:14
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Form: Covid-19 Severity Assessment

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:18
DataPoint Un-verified.	Whitney West (b) (4)	06 Dec 2020 00:40:18
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	06 Dec 2020 00:40:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:18
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	08 Dec 2020 22:42:39
User entered '28 Nov 2020' reason for change: New Information	Whitney West (b) (4)	08 Dec 2020 22:42:39
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	08 Dec 2020 22:34:25
User entered '28 Dec 2020' reason for change: New Information	Whitney West (b) (4)	08 Dec 2020 22:34:25
DataPoint Un-verified.	Whitney West (b) (4)	06 Dec 2020 00:40:18
User entered '01 Dec 2020' reason for change: New Information	Whitney West (b) (4)	06 Dec 2020 00:40:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:18
DataPoint Un-verified.	Whitney West (b) (4)	13 Apr 2021 13:45:07
User entered '25 Jan 2021' reason for change: Per Query Resolution	Whitney West (b) (4)	13 Apr 2021 13:45:07
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:18
DataPoint Un-verified.	Whitney West (b) (4)	06 Dec 2020 00:40:18
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	06 Dec 2020 00:40:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:18
DataPoint Un-verified.	Whitney West (b) (4)	06 Dec 2020 00:40:18
User entered '01 Dec 2020' reason for change: New Information	Whitney West (b) (4)	06 Dec 2020 00:40:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

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Generated On: 09 Jun 2021 16:18:59

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:18
DataPoint Un-verified.	Whitney West (b) (4)	13 Apr 2021 13:45:07
User entered '01 Jan 2021' reason for change: Data Entry Error	Whitney West (b) (4)	13 Apr 2021 13:45:07
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Generated On: 09 Jun 2021 16:18:59

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

US3272026

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Generated On: 09 Jun 2021 16:18:59

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

US3272026

Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

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Generated On: 09 Jun 2021 16:18:59

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

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Generated On: 09 Jun 2021 16:18:59

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:18
DataPoint Un-verified.	Whitney West (b) (4)	08 Dec 2020 22:34:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Whitney West (b) (4)	08 Dec 2020 22:34:25
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:18
DataPoint Un-verified.	Whitney West (b) (4)	08 Dec 2020 22:34:25
User entered '30 Nov 2020' reason for change: New Information	Whitney West (b) (4)	08 Dec 2020 22:34:25
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

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Generated On: 09 Jun 2021 16:18:59

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

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[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered 'Yes (Y)'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

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Generated On: 09 Jun 2021 16:18:59

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:18:59

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:18
DataPoint Un-verified.	Whitney West (b) (4)	13 Apr 2021 13:45:07
User entered '12 Feb 2021' reason for change: Per Query Resolution	Whitney West (b) (4)	13 Apr 2021 13:45:07
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:08
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:07:04

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:18:59

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:37:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:42:19
User entered 'Yes (Y)'	Whitney West (b) (4)	19 Nov 2020 22:07:20

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:18:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User closed query 'Per GCL LAB reconciliation: Saliva: DAY 3 labelled sample dated 14NOV2020 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:09:23
Query 'Per GCL LAB reconciliation: Saliva: DAY 3 labelled sample dated 14NOV2020 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' answered with 'sample shipped' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 21:40:06
User opened query 'Per GCL LAB reconciliation: Saliva: DAY 3 labelled sample dated 14NOV2020 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:58:45
User accepted default value 'Day 3 (Day 3)'	Whitney West (b) (4)	04 Feb 2021 20:49:19

US3272026

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:18:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:26
User closed query 'Per GCL LAB reconciliation: Saliva Re-query : DAY 3 labelled sample dated 14NOV2020 is still missing in PPD. Please provide the "Accession # and Tracking number" with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 09:00:41
Query 'Per GCL LAB reconciliation: Saliva Re-query : DAY 3 labelled sample dated 14NOV2020 is still missing in PPD. Please provide the "Accession # and Tracking number" with the shipping date to track the sample in PPD. Thank you.' answered with 'Participant was bring in sample when he was directed to ED for emergent conditions. ' (Site from DM).	Whitney West (b) (4) (b) (4)	19 Feb 2021 14:05:23
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4) (b) (4)	19 Feb 2021 14:04:59
User opened query 'Per GCL LAB reconciliation: Saliva Re-query : DAY 3 labelled sample dated 14NOV2020 is still missing in PPD. Please provide the "Accession # and Tracking number" with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:10:13
User entered 'Yes (Y)'	Whitney West (b) (4) (b) (4)	04 Feb 2021 20:49:19

US3272026

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:18:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:26
User entered empty; reason for change New Information	Whitney West (b) (4)	19 Feb 2021 14:04:59
User entered '14 Nov 2020' reason for change: New Information	Whitney West (b) (4)	04 Feb 2021 20:50:34
User entered empty.	Whitney West (b) (4)	04 Feb 2021 20:49:19

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:18:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User closed query 'Per GCL LAB reconciliation: Saliva: DAY 5 labelled sample dated 16NOV2020 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Than' (Site from DM).		19 Feb 2021 11:10:18
Query 'Per GCL LAB reconciliation: Saliva: DAY 5 labelled sample dated 16NOV2020 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Than' answered with 'sample shipped' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 21:40:17
User opened query 'Per GCL LAB reconciliation: Saliva: DAY 5 labelled sample dated 16NOV2020 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Than' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:58:58
User accepted default value 'Day 5 (Day 5)'	Whitney West (b) (4)	04 Feb 2021 20:49:19

US3272026

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:18:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:26
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	19 Feb 2021 14:04:59
User entered 'Yes (Y)'	Whitney West (b) (4)	04 Feb 2021 20:49:19

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:18:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:26
User closed query 'Per GCL LAB reconciliation: Saliva Re-query : DAY 5 labelled sample dated 16NOV2020 is still missing in PPD. Please provide the "Accession # and Tracking number" with the shipping date to track the sample in PPD. Thank you.' (Site from DM).		24 Feb 2021 09:00:46
Query 'Per GCL LAB reconciliation: Saliva Re-query : DAY 5 labelled sample dated 16NOV2020 is still missing in PPD. Please provide the "Accession # and Tracking number" with the shipping date to track the sample in PPD. Thank you.' answered with 'Collected at time of illness- not delivered as participant became gravely ill and ultimately transferred. ' (Site from DM).	Whitney West (b) (4)	19 Feb 2021 14:06:03
User entered empty; reason for change New Information	Whitney West (b) (4)	19 Feb 2021 14:04:59
User opened query 'Per GCL LAB reconciliation: Saliva Re-query : DAY 5 labelled sample dated 16NOV2020 is still missing in PPD. Please provide the "Accession # and Tracking number" with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:10:34
User entered '16 Nov 2020' reason for change: New Information	Whitney West (b) (4)	04 Feb 2021 20:50:34
User entered empty.	Whitney West (b) (4)	04 Feb 2021 20:49:19

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:18:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User closed query 'Per GCL LAB reconciliation: Saliva: DAY 7 labelled sample dated 18NOV2020 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:10:41
Query 'Per GCL LAB reconciliation: Saliva: DAY 7 labelled sample dated 18NOV2020 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' answered with 'sample shipped' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 21:40:27
User opened query 'Per GCL LAB reconciliation: Saliva: DAY 7 labelled sample dated 18NOV2020 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:59:18
User accepted default value 'Day 7 (Day 7)'	Whitney West (b) (4)	04 Feb 2021 20:49:19

US3272026

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:18:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:26
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	19 Feb 2021 14:04:59
User entered 'Yes (Y)'	Whitney West (b) (4)	04 Feb 2021 20:49:19

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:18:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:26
User closed query 'Per GCL LAB reconciliation: Saliva Re-query : DAY 7 labelled sample dated 18NOV2020 is still missing in PPD. Please provide the "Accession # and Tracking number" with the shipping date to track the sample in PPD. Thank you.' (Site from DM).		24 Feb 2021 09:00:50
Query 'Per GCL LAB reconciliation: Saliva Re-query : DAY 7 labelled sample dated 18NOV2020 is still missing in PPD. Please provide the "Accession # and Tracking number" with the shipping date to track the sample in PPD. Thank you.' answered with 'Collected at time of illness by participant who went on to become gravely ill and was unable to deliver.' (Site from DM).	Whitney West (b) (4)	19 Feb 2021 14:06:44
User entered empty; reason for change New Information	Whitney West (b) (4)	19 Feb 2021 14:04:59
User opened query 'Per GCL LAB reconciliation: Saliva Re-query : DAY 7 labelled sample dated 18NOV2020 is still missing in PPD. Please provide the "Accession # and Tracking number" with the shipping date to track the sample in PPD. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:10:59
User entered '18 Nov 2020' reason for change: Data Entry Error	Whitney West (b) (4)	04 Feb 2021 20:50:34
User entered empty.	Whitney West (b) (4)	04 Feb 2021 20:49:19

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:18:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User accepted default value 'Day 9 (Day 9)'	Whitney West (b) (4) (b) (4)	04 Feb 2021 20:49:19

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:18:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:26
User entered 'No (N)'	Whitney West (b) (4)	04 Feb 2021 20:49:19

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:18:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:26
User entered empty.	Whitney West (b) (4)	04 Feb 2021 20:49:19

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:18:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User accepted default value 'Day 14 (Day 14)'	Whitney West (b) (4) (b) (4)	04 Feb 2021 20:49:19

US3272026

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:18:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:26
User entered 'No (N)'	Whitney West (b) (4)	04 Feb 2021 20:49:19

US3272026

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:18:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:26
User entered empty.	Whitney West (b) (4)	04 Feb 2021 20:49:19

US3272026

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:18:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User accepted default value 'Day 21 (Day 21)'	Whitney West (b) (4) (b) (4)	04 Feb 2021 20:49:19

US3272026

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:18:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:26
User entered 'No (N)'	Whitney West (b) (4)	04 Feb 2021 20:49:19

US3272026

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:18:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:26
User entered empty.	Whitney West (b) (4)	04 Feb 2021 20:49:19

US3272026

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:18:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User accepted default value 'Day 28 (Day 28)'	Whitney West (b) (4) (b) (4)	04 Feb 2021 20:49:19

US3272026

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:18:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:26
User entered 'No (N)'	Whitney West (b) (4)	04 Feb 2021 20:49:19

US3272026

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:18:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:18:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:26
User entered empty.	Whitney West (b) (4)	04 Feb 2021 20:49:19

US3272026

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Please reconcile and enter saliva log' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 03:21:08
Query 'Please reconcile and enter saliva log' answered with 'Subject is in hospital, no saliva has been collected.' (Site from CRA).	Kayla Flege (b) (4)	23 Nov 2020 22:22:06
User opened query 'Please reconcile and enter saliva log' (Site from CRA).	(b) (4)	(b) (4), (b) (6)
DataPoint Verified.		21 Nov 2020 19:28:01
		20 Nov 2020 15:39:28
User entered 'Yes (Y)'		12 Nov 2020 21:05:30

US3272026

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:28
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:05:30

US3272026

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:28
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Nov 2020 21:05:30

US3272026

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:37
User entered 'SICKD1'	System	12 Nov 2020 21:05:30

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '13:10'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User entered '12 Nov 2020 13:10'	System	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '178' cm	(b) (4), (b) (6)	12 Nov 2020 21:11:05
DataPoint set to visible.	System	12 Nov 2020 21:05:30

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '122.9' kg	(b) (4), (b) (6)	12 Nov 2020 21:11:05
DataPoint set to visible.	System	12 Nov 2020 21:05:30

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '97.4' F	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '84'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User entered 'bpm'	System	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '18'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User entered 'breaths/min'	System	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '132'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User entered 'mmHg'	System	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:42
User entered '83'	(b) (4), (b) (6)	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45
User entered 'mmHg'	System	12 Nov 2020 21:11:05

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45

US3272026

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:45

US3272026

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 21:11:14

US3272026

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:55
User entered '12 Nov 2020'		12 Nov 2020 21:11:14

US3272026

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:18:59

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:59
User entered 'Yes (Y)'		12 Nov 2020 21:11:22

US3272026

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 16:18:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:17:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:59
User entered '12 Nov 2020'		12 Nov 2020 21:11:22

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:58
User entered 'No (N)'	Ashley Bell (b) (4)	31 Mar 2021 19:47:25

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:58
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:47:25

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:36:58
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:47:25

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered 'SICKD28'	System	31 Mar 2021 19:47:25

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:07
User entered 'No (N)'	Ashley Bell (b) (4)	31 Mar 2021 19:47:34

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:07
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:47:34

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:07
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:47:34

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	31 Mar 2021 19:47:34

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:07
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:47:34

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:07
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:47:34

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:07
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:47:34

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:07
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:47:34

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	31 Mar 2021 19:47:34

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:07
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:47:34

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	31 Mar 2021 19:47:34

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:07
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:47:34

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	31 Mar 2021 19:47:34

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:07
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:47:34

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	31 Mar 2021 19:47:34

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:18:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:13
User entered 'No (N)'	Ashley Bell (b) (4)	31 Mar 2021 19:47:37

US3272026

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:18:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:13
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:47:37

US3272026

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 16:18:59

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:17
User entered 'No (N)'	Ashley Bell (b) (4)	31 Mar 2021 19:47:46

US3272026

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 16:18:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:37:17
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:47:46

US3272026

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

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:14
User entered 'Yes (Y)'	Ashley Bell (b) (4)	31 Mar 2021 19:44:31

US3272026

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

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:14
User entered '25 Mar 2021'	Ashley Bell (b) (4)	31 Mar 2021 19:44:31

US3272026

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

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:14
User entered 'Clinic (Clinic)'	Ashley Bell (b) (4)	31 Mar 2021 19:44:31

US3272026

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

Form: Visit Date

Generated On: 09 Jun 2021 16:18:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User entered 'UNBLND_DECIDE'	System	31 Mar 2021 19:44:31

US3272026

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:27
User entered '25 Mar 2021'	Ashley Bell (b) (4)	31 Mar 2021 19:44:56

US3272026

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:59

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:27
User entered '0'	Ashley Bell (b) (4)	31 Mar 2021 19:44:56

US3272026

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:59

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:27
User entered 'Yes (Y)'	Ashley Bell (b) (4)	31 Mar 2021 19:44:56

US3272026

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:59

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:27
User entered 'Amendment 6 or later (Amendment 6 or later)'	Ashley Bell (b) (4)	31 Mar 2021 19:44:56

US3272026

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:27
User entered '25 Mar 2021'	Ashley Bell (b) (4)	31 Mar 2021 19:44:56

US3272026

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:27
User entered 'Placebo (Placebo)'	Ashley Bell (b) (4)	31 Mar 2021 19:44:56

US3272026

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:59

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:27
User entered 'Placebo (Placebo)'	Ashley Bell (b) (4)	31 Mar 2021 19:44:56

US3272026

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:59

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:27
User entered 'Placebo (Placebo)'	Ashley Bell (b) (4)	31 Mar 2021 19:44:56

US3272026

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:27
User entered 'No (N)'	Ashley Bell (b) (4)	31 Mar 2021 19:44:56

US3272026

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:59

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User entered 'I'	System	31 Mar 2021 19:44:56

US3272026

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

Form: Unblinding

Generated On: 09 Jun 2021 16:18:59

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User entered empty.	System	31 Mar 2021 19:44:56

US3272026

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:34
User entered 'Yes (Y)'	Ashley Bell (b) (4)	31 Mar 2021 19:45:10

US3272026

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:34
User entered '25 Mar 2021'	Ashley Bell (b) (4)	31 Mar 2021 19:45:10

US3272026

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:34
User entered '13:19'	Ashley Bell (b) (4)	31 Mar 2021 19:45:10

US3272026

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User entered '25 Mar 2021 13:19'	System	31 Mar 2021 19:45:10

US3272026

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:18:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:39
User entered 'Yes (Y)'	Ashley Bell (b) (4)	31 Mar 2021 19:45:20

US3272026

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:18:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:39
User entered '25 Mar 2021'	Ashley Bell (b) (4)	31 Mar 2021 19:45:20

US3272026

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:18:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:38:39
User entered '13:31'	Ashley Bell (b) (4)	31 Mar 2021 19:45:20

US3272026

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:51:04
User entered '25 Mar 2021 13:31'	System	31 Mar 2021 19:45:20

US3272026

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:18:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User closed query 'Consider adding the following conmeds as noted in the source. Cisatracurium Nimbex) infusion Pecedex IV infusion Fentanyl infusion nicardipine infusion ' (Site from CRA).		04 Feb 2021 16:41:26
Query 'Consider adding the following conmeds as noted in the source. Cisatracurium Nimbex) infusion Pecedex IV infusion Fentanyl infusion nicardipine infusion ' answered with 'Cisatracurium is listed as Med #25, Pecedex is #23, and Fentanyl is #27.	Whitney West (b) (4) (b) (4)	21 Dec 2020 23:22:32
Will add nicardipine- looking for confirmation that participant actually received this- is not listed as medication in the transfer hospital. ' (Site from CRA).		
User opened query 'Consider adding the following conmeds as noted in the source. Cisatracurium Nimbex) infusion Pecedex IV infusion Fentanyl infusion nicardipine infusion ' (Site from CRA).	(b) (4), (b) (6)	17 Dec 2020 19:18:25
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:17
Query 'Please enter End of Study pages to reflect subject passed away on 17Nov2020' canceled (Site from CRA).		20 Nov 2020 00:15:20
User opened query 'Please enter End of Study pages to reflect subject passed away on 17Nov2020' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 00:14:11
User signature succeeded.	Adam Brosz (b) (4)	17 Nov 2020 00:48:06
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 23:16:59
User entered 'Yes (Y)' reason for change: Data Entry Error		16 Nov 2020 23:16:59

US3272026

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:18:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:57:48
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:48:16

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
Reviewed for Safety.		17 Nov 2020 19:11:00
User entered 'USA-US070-2020-mRNA-1273-P301000019'	System	17 Nov 2020 19:10:49
User entered 'New'	(b) (4), (b) (6)	17 Nov 2020 19:10:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 19:50:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 19:50:50
Data point term sent to Coder	System	17 Nov 2020 19:50:17
Coding entries removed.	(b) (4), (b) (6)	17 Nov 2020 19:49:22
User entered 'COVID19' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 19:49:22
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 03:49:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 03:49:59
Data point term sent to Coder	System	16 Nov 2020 23:25:33
User entered 'Covid19 like illness'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'Yes (Y)'		16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'No (N)'		16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User closed query 'Please reconcile as there was an illness visit and subject has to be symptomatic to come in for illness visits' (Site from CRA).		20 Nov 2020 00:14:56
Query 'Please reconcile as there was an illness visit and subject has to be symptomatic to come in for illness visits' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4) (b) (4)	19 Nov 2020 21:11:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Flege (b) (4) (b) (4)	19 Nov 2020 21:11:46
User opened query 'Please reconcile as there was an illness visit and subject has to be symptomatic to come in for illness visits' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:23:35
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '08 Nov 2020'		16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered empty.		16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:45:35
DataPoint Un-verified.	Whitney West (b) (4)	15 Feb 2021 16:47:41
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	15 Feb 2021 16:47:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'Yes (Y)'		16 Nov 2020 23:24:49

US3272026

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:45:32
User entered '29 Dec 2020' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 22:30:37
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:53:22
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Participant has returned home. Still on 1L/NC for everyday, 3L/NC for activity, and 2L/NC at night. No plan or prediction for weaning of further O2, seeming new baseline. Ongoing PT for strengthening. ' (Site from Safety).	Whitney West (b) (4)	15 Feb 2021 16:47:49
DataPoint Un-verified.	Whitney West (b) (4)	15 Feb 2021 16:47:41
User entered '12 Feb 2021' reason for change: New Information	Whitney West (b) (4)	15 Feb 2021 16:47:41
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 15:49:57
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 17:12:07
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Ongoing. ' (Site from Safety).	Whitney West (b) (4)	14 Dec 2020 23:33:10
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 01:48:37

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered empty.		16 Nov 2020 23:24:49

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Folder: Adverse Events

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:45:29
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 14:22:54
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'A new baseline has been obtained. Participant was dismissed to a rehab hospital and is being transitioned home. He has ongoing treatment to strengthen and rehabilitate, but baseline will not be enhanced by further medical symptom relief. ' (Site from Safety).	Whitney West (b) (4)	04 Feb 2021 21:06:33
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:40:41
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:29:46
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered empty.		16 Nov 2020 23:24:49

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	16 Nov 2020 23:24:49

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'Grade 4 (Grade 4)'		16 Nov 2020 23:24:49

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'Yes (Y)'		16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '0'		16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'PV Query: Please provide rationale for seriousness assessment of Life-threatening for event COVID19.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 15:57:39
Query 'PV Query: Please provide rationale for seriousness assessment of Life-threatening for event COVID19.' answered with 'Patient was initiated on bipap 16NOV2020. Intubated 01DEC2020 and began on ECMO 16NOV2020. Acute respiratory failure diagnosed 16NOV2020. ' (Site from Safety).	Whitney West (b) (4)	06 Dec 2020 00:55:36
User opened query 'PV Query: Please provide rationale for seriousness assessment of Life-threatening for event COVID19.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 01:53:18
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'I'		16 Nov 2020 23:24:49

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
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).		20 Nov 2020 08:03:39
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated' (Site from System).	Kayla Flege (b) (4) (b) (4)	19 Nov 2020 21:12:01
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	16 Nov 2020 23:24:49
User entered '1'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '16 Nov 2020'		16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:45:02
User closed query 'PV Query: Please confirm hospitalization discharge date for AE #1, #2, #4, #5. Query answer of 22 Jan 2021 conflicts with what was reported in AE # 6 case narrative.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:53:33
Query 'PV Query: Please confirm hospitalization discharge date for AE #1, #2, #4, #5. Query answer of 22 Jan 2021 conflicts with what was reported in AE # 6 case narrative.' answered with 'Left hospital for the first time 20JAN2021. ' (Site from Safety).	Whitney West (b) (4)	15 Feb 2021 16:51:30
User opened query 'PV Query: Please confirm hospitalization discharge date for AE #1, #2, #4, #5. Query answer of 22 Jan 2021 conflicts with what was reported in AE # 6 case narrative.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide the hospital discharge date when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 16:40:12
User entered '20 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	12 Feb 2021 16:39:53
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	06 Feb 2021 23:37:46
User closed query 'Per CDM: Thanks for the response. Please update as soon as the data is available.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 16:40:48
Query 'Per CDM: Thanks for the response. Please update as soon as the data is available.' answered with 'Will do. Subject has not been discharged as of today.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 16:31:06
User opened query 'Per CDM: Thanks for the response. Please update as soon as the data is available.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 22:05:23
	Kayla Flege (b) (4)	24 Nov 2020 15:33:23
	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 13:55:07

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: 'Subject is currently still hospitalized for recovery'. Please update 'Hospital Discharge Date' once data becomes known. Thanks' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:54:48
		20 Nov 2020 15:45:44
Query 'Per CDM: 'Subject is currently still hospitalized for recovery'. Please update 'Hospital Discharge Date' once data becomes known. Thanks' answered with 'subject is still currently in hospital' (Site from DM).		20 Nov 2020 14:51:21
User opened query 'Per CDM: 'Subject is currently still hospitalized for recovery'. Please update 'Hospital Discharge Date' once data becomes known. Thanks' (Site from DM).		20 Nov 2020 08:03:36
User entered empty.		16 Nov 2020 23:24:49

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 21:51:16
User entered 'No (N)'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint Un-verified.	Whitney West (b) (4)	06 Dec 2020 00:57:06
User entered '20' reason for change: New Information	Whitney West (b) (4)	06 Dec 2020 00:57:06
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '2' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 21:51:16
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '1' reason for change: Data Entry Error		17 Nov 2020 19:49:22
User entered '0'		16 Nov 2020 23:24:49

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '0'		16 Nov 2020 23:24:49

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '0'		16 Nov 2020 23:24:49

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User closed query 'Please verify if PI feels this is related to IP' (Site from CRA).	(b) (4)	20 Nov 2020 00:15:40
Query 'Please verify if PI feels this is related to IP' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4)	19 Nov 2020 21:12:07
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 21:11:46
User opened query 'Please verify if PI feels this is related to IP' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 01:22:21
User entered 'Related (RELATED)'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User closed query 'Please verify if PI feels this is related to study procedure as subject is >2 months from last dose' (Site from CRA).		20 Nov 2020 00:15:42
Query 'Please verify if PI feels this is related to study procedure as subject is >2 months from last dose' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4)	19 Nov 2020 21:12:13
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 21:11:46
User opened query 'Please verify if PI feels this is related to study procedure as subject is >2 months from last dose' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 01:22:53
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 01:22:24
DataPoint Verified.		17 Nov 2020 01:22:23
User entered 'Related (RELATED)'		16 Nov 2020 23:24:49

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User closed query 'Per CDM: Action Taken with Investigational Product = NONE however, adverse event started AFTER last dose? Please review and update accordingly as per CCG's.' (Site from DM). Query 'Per CDM: Action Taken with Investigational Product = NONE however, adverse event started AFTER last dose? Please review and update accordingly as per CCG's.' answered with 'Not applicable.' (Site from DM).	Whitney West (b) (4)	06 Dec 2020 00:57:34
DataPoint Un-verified.	Whitney West (b) (4)	06 Dec 2020 00:57:06
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Whitney West (b) (4)	06 Dec 2020 00:57:06
User opened query 'Per CDM: Action Taken with Investigational Product = NONE however, adverse event started AFTER last dose? Please review and update accordingly as per CCG's.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 13:29:15
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'None (NONE)'		16 Nov 2020 23:24:49

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		19 Nov 2020 21:11:46
User entered '0' reason for change: Data Entry Error	Kayla Flege (b) (4)	19 Nov 2020 21:11:46
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4) System	17 Nov 2020 19:49:22
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Nov 2020 23:27:58
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 23:27:58
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Nov 2020 23:24:49
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '1' reason for change: Data Entry Error		17 Nov 2020 19:49:22
User entered '0'		16 Nov 2020 23:24:49

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
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.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 15:08:33
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.' answered with 'Updating per request.' (Site from DM).	Whitney West (b) (4)	09 Dec 2020 22:39:22
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.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 05:01:11
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered '1' reason for change: Data Entry Error		17 Nov 2020 19:49:22
User entered '0'		16 Nov 2020 23:24:49

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:45:09
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		16 Feb 2021 17:52:28
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'New baseline. ' (Site from Safety).	Whitney West (b) (4)	15 Feb 2021 16:51:40
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Whitney West (b) (4)	15 Feb 2021 16:47:41
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Whitney West (b) (4)	06 Feb 2021 23:03:00
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:40:58
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		01 Dec 2020 01:48:49
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 21:51:16
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 23:26:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 23:26:17
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 23:26:17
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 23:24:49

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[Outcome](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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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)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:45:11
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	15 Feb 2021 16:51:08
DataPoint Un-verified.	Whitney West (b) (4)	15 Feb 2021 16:51:08
User entered 'Ongoing supplemental O2 needs. 1L/NC at rest, 3L/NC c activity, 2L/NC at night. Continuing with PT for strengthening.' reason for change: New Information	Whitney West (b) (4)	15 Feb 2021 16:51:08
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	15 Feb 2021 16:47:41
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User entered empty.		16 Nov 2020 23:24:49

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:45:16

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'ADMITTED FOR ARDS D/T COVID-19 VIRUS. DIAGNOSED WITH COVID PNEUMONIA IN MID-NOVEMBER 2020 AND SUBSEQUENTLY DEVELOPED RESPIRATORY FAILURE D/T ASSOCIATED ARDS AND REQUIRED EMERGENT INTUBATION AT THE END OF THE MONTH DUE TO SEVERE HYPOXIA. DESPITE MAXIMAL VENT SETTINGS, THE PATIENT COULD NOT MAINTAIN ADEQUATE OXYGEN SATURATION AND WAS SENT TO A REGIONAL HOSPITAL AT THE BEGINNING OF DECEMBER FOR EVALUATION FOR VV ECMO. PARTICIPANT WAS CANNULATED AND EVENTUALLY REQUIRED TRACHEOSTOMY D/T PROLONGED VENTILATION REQUIREMENTS. ECMO WAS DECANNULATED 01JAN2021. HOSPITAL COURSE WAS COMPLICATED BY VRE BACTEREMIA, TRACH SITE BLEEDING, EPISTAXIS AND THROMBOCYTOPENIA WITH BOTH HEME/ONC AND ID ON BOARD. PARTICIPANT SEROTONIN RELEASE ASSAY IS NEGATIVE MAKING HIT LESS LIKELY. PARTICIPANT COMPLETED ANTIBIOTICS AND WAS STARTED ON PREDNISONE WITH CONCERN CAP. ON PREDNISONE TAPER WITH BACTRIM ON BOARD. DISMISSED TO LOCAL REHAB FACILITY WHERE HE HAD HEMORRHAGING FROM HIS TRACHEA AND WAS TRANSFERRED BACK FOR EVALUATION. HEMORRHAGE RESOLVED WITHOUT INTERVENTION, TRACHEOSTOMY DECANNULATION 25JAN2021. TUBE FEEDINGS STOPPED AS PO RESUMED. TRANSFERRED BACK TO REHAB. SUPPLEMENTAL 1-3L/NC WITH ACTIVITY. Discharged home 11FEB2021.' reason for change: New Information	Whitney West (b) (4)	15 Feb 2021 16:51:08

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Audit	User	Time (GMT)
User entered 'Admitted for ARDS d/t COVID-19 virus. Diagnosed with Covid pneumonia in mid-November 2020 and subsequently developed respiratory failure d/t associated ARDS and required emergent intubation at the end of the month due to severe hypoxia. Despite maximal vent settings, the patient could not maintain adequate oxygen saturation and was sent to a regional hospital at the beginning of December for evaluation for VV ECMO. Participant was cannulated and eventually required tracheostomy d/t prlonged ventilation requirements. ECMO was decannulated 01JAN2021. Hospital course was complicated by VRE bacteremia, trach site bleeding, epistaxis and thrombocytopenia with both heme/onc and ID on board. Participant serotonin release assay is negative making HIT less likely. Participant completed antibiotics and was started on prednisone with concern CAP. On prednisone taper with Bactrim on board. Dismissed to local rehab facility where he had hemorrhaging from his trachea and was transferred back for evaluation. Hemorrhage resolved without intervention, tracheostomy decannulation 25JAN2021. Tube feedings stopped as PO resumed. Transferred back to rehab. Supplemental 1-3L/NC with activity, likely discharge to home 11FEB2021.'	Whitney West (b) (4)	06 Feb 2021 23:37:46
reason for change: New Information DataPoint Un-verified.	Whitney West (b) (4)	06 Feb 2021 23:02:28

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Audit	User	Time (GMT)
User entered '16NOV2020- PCT CALLED AND REPORT 02 IN 80S%. DIRECTED TO ER FOR SUSTAINED HYPOXIA 78% ON ROOM AIR. PCT ESCALATED TO BIPAP WITH 02 75% AND TRANSFERRED TO ICU. CHEST X-RAY-BILATERAL PNEUMONIA, CT ANGIO R/O LARGE PE, D-DIMER NEGATIVESTARTED ON ALBUTEROL SULFATE, DELTASONE, CEFTRIAZONE, AZITHROMYCIN, DEXAMETHASONE, ENOXAPARIN, REMDESEVIR STARTED UPON ADMISSION. LAB REVEALS CRT 1.64- ACUTE KIDNEY INJURY- HYDRATION STARTED THEN STOPPED. BEGINS LORAZEPAM FOR ANXIETY SECONDARY TO OXYGEN MASKS. CONVALESCENT PLASMA. LASIX FOR EDEMA. 23NOV BIPAP 100 FIO2. BLOOD AND SPUTUM CULTURES NEGATIVE. ELEVATED DDIMER- KIDNEY/LUNG FUNCTION R/O SCANS. INCREASED ENOXAPARIN. EKG FOR STARTING RUXOLITINIB CLINICAL DRUG INITIATION ON 24NOV2020. CONTINUED DETERIORATION. DEXMEDETOMIDINE INFUSION STARTED 26NOV- STILL SYMPTOMATIC AND FULL BIPAP SUPPORT. STARTED SUPPLEMENTS FOR IMMUNE SUPPORT ON 27NOV, INCREASED STEROIDS. 28NOV EMERGENT INTUBATION AFTER SEVERE COUGHING SPELL C EXTREME RESP DISTRESS. TACHYPNEIC, TACHYCARDIC, AND CYANOTIC APPEARANCE. ID FOLLOWING. INHALED EPOPROSTENOL. OG, ETT, RIGHT RAD ART LINE. MIDLINE INSERTED. EPOPROSTENOL, FENTANYL, PROPOFOL INITIATED. VASOPRESSORS STARTED AND STOPPED. ACUTE KIDNEY INJURY RESOLVED. SPUTUM CULTURES NEGATIVE AGAIN. ESCALATION TO ECMO, TRANSFERRED TO REGIONAL HOSPITAL 01DEC2020. TTE, BRONCH, DOPPLERS TO PREP FOR ECMO PLACEMENT. LASIX	Whitney West (b) (4)	06 Feb 2021 23:02:28

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Audit	User	Time (GMT)
<p>CONTINUED. TUBE FEEDINGS WITH Q6 INSULIN. NICARDIPINE STARTED AND STOPPED. VV ECMO PLACEMENT 02DEC2020. Right-sided epistaxis simultaneously began with oxymetazoline and rhino rocket placement 02DEC2020, 13DEC2020, and 21DEC2020 while on a hepar. 02DEC2020 PCR STILL POSITIVE FOR COVID-19. 04DEC2020 bronchoscopy cultures grew Pseudomonas- vancomycin stopped and cefepime continued. Tracheostomy performed by ENT 10DEC2020. ECMO circuit exchange and bronchoscopy 14DEC2020 showed large mucous plug. 17DEC2020 ECMO circuit exchange. 22DEC2020 cefepime completed. 23DEC2020 bronchoscopy performed, cultured pseudomonas again.' reason for change: New Information User closed query 'Per DM CLR: SAE Narrative = PATIENT STARTED ON BIPAP WITH O2 75% . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). DataPoint Verified.</p> <p>User closed query 'PV Query: Please provide the results of any relevant laboratory tests and/or other relevant exams performed to diagnose, confirm, and/or monitor the event.' (Site from Safety).</p>	(b) (4), (b) (6)	22 Dec 2020 11:03:52
		17 Dec 2020 17:37:52
		16 Dec 2020 14:06:32

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Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any relevant laboratory tests and/or other relevant exams performed to diagnose, confirm, and/or monitor the event.' answered with 'CXR-bilateral pneumonia, CTA r/o large PE, LDH:589. Creat 1.64. 17NOV2020-Creat:1.4. Sputum culture. 18NOV- BUN 35, Creat 1.43, Ca 8.1, Alb 2.5 (remains low), AST 45. 19NOV2020- Creat: 1.34, Alb 2.4, AST 50, ALT- normal. WBC- 11.9. N0NOV2020- Creat: 1.43, BUN 41. 21NOV2020- Creat: 1.44, BUN 40. WBC: 15.5. 22NOV2020-Micro final report- no growth after 5 days. GFR: 82. 23NOV2020- Creat 1.34, BUN 40, Alb 2.6, WBC 16.9. Elevated D-dimer. CKD-No CTA chest. High O2 no VQ scan. EKG ordered for clinical trial drugs- ruxolitinib. 24NOV2020. Bipap 90%. 88% 99.2, 28, WBC: 16.5, LD: 698. 25NOV2020. Creatinine 1.38. ALT 95, Ca: 8.2, WBC: 16.2, CXRAY shows no interval improvement. Blood cultures- final report negative. Sputum negative. Repeat blood culture. LDL: 66. 26NOV2020- Creat 1.21, BUN 42, Ca 8.0. WBC 19. LDL: 573. 27NOV2020- WBC: 18.8. LDL: 737. 28NOV2020CXR- extensive bilateral infiltrates. BUN 31, Creat: 0.93, Ca: 8.3, Alb 2.4, WBC 28.1, Segs ABS: 24.2, Triglycerides: 245. Kidneys improving. ID- F/U blood cultures. GI feedings. LDL: 762 and triglycerides 245. 29NOV2020- WBC: 23.3, BUN: 31, Ca 8.1, Alb: 2.2. BP 101/70, 98.8, RR24, SpO2: 94%. Sputum negative, blood culture: negative. 30NOV2020- WBC 18.4, 12.4 hgb, hct 38.6, RBC 4.25. Sputum- final negative. FIO2- down to 80%. AKI resolved. 01DEC2020- WBC 19.1, Hgb 11.8, HCT 37.7, RBC 4.10, BUN 30, ALB: 2.0. Chest xray Bilateral opacities stable. TTE: for ECMO eval. bronchoscopy, cannulation, tte and le now. Wbc 30.4, HGB: 12.9, ALK PHos: 144, AST: 82. 02DEC2020. CXR unchanged. Wbc 18.8, hgb: 11.3, HCT 36.3, rbc 3.95. co2: 37.0, bun 28, Alb 2.1. Trig: 451. PCR- 02DEC2020- COVID-19 Detected. ' (Site from Safety).	Whitney West (b) (4)	15 Dec 2020 14:18:06

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Form: Adverse Events (1)

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Audit	User	Time (GMT)
User closed query 'PV Query: Please report if the subject had any known exposure to COVID-19' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 20:15:08
User closed query 'PV Query: Please send a hospital discharge summary and or pertinent consult notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 20:15:03
Query 'PV Query: Please send a hospital discharge summary and or pertinent consult notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Participant transferred to another hospital. Discharge papers were obtained for this discharge. The patient is at another hospital and will be there for multiple weeks if not substantially longer. I will send the second set of records once they become available.' (Site from Safety).	Whitney West (b) (4)	11 Dec 2020 17:35:45
Query 'PV Query: Please report if the subject had any known exposure to COVID-19' answered with 'Participant had no known exposure before testing positive.' (Site from Safety).	Whitney West (b) (4)	11 Dec 2020 17:12:32
User closed query 'PV Query: Please provide clinical course of the event.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 14:11:06
User closed query 'PV Query: Has COVID-19 testing been repeated at any lab or while subject was hospitalized? Please provide dates and results of COVID-19 diagnostic testing (swab or other)' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 14:10:59
User closed query 'PV Query: Please indicate any risk factors the subject had for the development of COVID-19, (advanced age, obesity, underlying cardiac conditions, congregate living, recent exposure, cancer, immunosuppression, hypertension, diabetes, asthma, other respiratory conditions, stressful situations, etc).' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 14:10:53

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Audit	User	Time (GMT)
User closed query 'PV Query: Please assess if acute respiratory failure, acute kidney injury, acute respiratory distress syndrome, multifocal pneumonia met criteria for SAE/AE reporting?' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 14:10:48
Query 'Per DM CLR: SAE Narrative = PATIENT STARTED ON BIPAP WITH O2 75% . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'I will add this to ConProc. Does Bipap count as one procedure? Or would it be counted as a daily procedure? ' (Site from DM).	Whitney West (b) (4)	11 Dec 2020 00:36:30
Query 'PV Query: Please assess if acute respiratory failure, acute kidney injury, acute respiratory distress syndrome, multifocal pneumonia met criteria for SAE/AE reporting?' answered with 'This falls within the clinical course of the initial COVID-19 and would not be reported as separate events. ' (Site from Safety).	Whitney West (b) (4)	11 Dec 2020 00:35:30
Query 'PV Query: Please indicate any risk factors the subject had for the development of COVID-19, (advanced age, obesity, underlying cardiac conditions, congregate living, recent exposure, cancer, immunosuppression, hypertension, diabetes, asthma, other respiratory conditions, stressful situations, etc).' answered with 'Participant has history of obesity and his wife is a clinic nurse. No other medical history. ' (Site from Safety).	Whitney West (b) (4)	10 Dec 2020 22:39:03
Query 'PV Query: Has COVID-19 testing been repeated at any lab or while subject was hospitalized? Please provide dates and results of COVID-19 diagnostic testing (swab or other)' answered with 'Once- 02DEC2020, participant was still positive. ' (Site from Safety).	Whitney West (b) (4)	10 Dec 2020 22:38:24
Query 'PV Query: Please provide clinical course of the event.' answered with 'Done. ' (Site from Safety).	Whitney West (b) (4)	10 Dec 2020 22:38:03

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Audit	User	Time (GMT)
User entered '16NOV2020- PCT called and report 02Whitney West in 80s%. Directed to ER for sustained hypoxia 78% on room air. PCT escalated to bipap with 02 75% and transferred to ICU. Chest x-ray-bilateral pneumonia, CT angio r/o large PE, d-dimer negativeStarted on albuterol sulfate, deltasone, ceftriaxone, azithromycin, dexamethasone, enoxaparin, remdesevir started upon admission. Lab reveals crt 1.64- acute kidney injury- hydration started then stopped. Begins lorazepam for anxiety secondary to oxygen masks. Convalescent plasma. Lasix for edema. 23NOV Bipap 100 FIO2. Blood and sputum cultures negative. Elevated ddimer- kidney/lung function r/o scans. Increased enoxaparin. EKG for starting ruxolitinib clinical drug initiation on 24NOV2020. Continued deterioration. Dexmedetomidine infusion started 26NOV- still symptomatic and full bipap support. Started supplements for immune support on 27NOV, increased steroids. 28NOV emergent intubation after severe coughing spell c extreme resp distress. Tachypneic, tachycardic, and cyanotic appearance. ID following. Inhaled epoprostenol. OG, ETT, right rad art line. Midline inserted. Epoprostenol, Fentanyl, Propofol initiated. Vasopressors started and stopped. Acute kidney injury resolved. Sputum cultures negative again. Need escalation to ECMO, transferred to regional hospital 01DEC2020. TTE, bronch, dopplers to prep for ECMO placement. Lasix continued. Tube feedings with q6 insulin. Nicardipine started and stopped. VV ECMO placement 02DEC2020. PCR on 02DEC2020 still positive for COVID-19. Per family report, participant received tracheostomy on 10DEC2020, still receiving treatment, medical team estimates multiple weeks before beginning to try to wean sedation on the participant. Still on ECMO and vent.' reason for change: New Information	(b) (4)	10 Dec 2020 22:37:36

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Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = PATIENT STARTED ON BIPAP WITH O2 75% . However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	08 Dec 2020 05:01:05
	Whitney West (b) (4)	06 Dec 2020 00:54:23
User entered 'PCT CALLED AND REPORTED O2 SATURATION IN THE 80S%. DIRECTED PATIENT TO EMERGENCY DEPARTMENT FOR SUSTAINED HYPOXIA. FOUND TO BE 78% ON RA. PATIENT STARTED ON BIPAP WITH O2 75% AND TRANSFERRED TO ICU. DX WITH ACUTE RESPIRATORY FAILURE, AKI, ARDS, AND MULTIFOCAL PNEUMONIA.	Whitney West (b) (4)	06 Dec 2020 00:54:23
WAS STARTED ON ALBUTEROL SULFATE, DELTASONE, CEFTRIAZONE, AZITHROMYCIN, DEXAMETHASONE, EXNOXAPARIN, REMDESIVIR UPON ADMISSION. REQUESTING FURTHER INFORMATION.		
Ongoing contact problems due to participant becoming too dyspneic to speak and family representative failing to return contact. Participant continued to have respiratory failure and was intubated 01DEC2020 per family report. Life-flight to another facility due to ongoing oxygenation issues and was started on ECMO on the same day 01DEC2020. Family reports participant still on ECMO, intubation settings are being weaned down, participant still sedated. Family does not know medications, settings, or vitals. Third request for information sent to local hospital. New hospital information obtained and faxed 05DEC2020.' reason for change: New Information		
User opened query 'PV Query: Please provide the results of any relevant laboratory tests and/or other relevant exams performed to diagnose, confirm, and/or monitor the event.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 01:56:51

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Audit	User	Time (GMT)
User opened query 'PV Query: Please provide clinical course of the event.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 01:56:41
User opened query 'PV Query: Has COVID-19 testing been repeated at any lab or while subject was hospitalized? Please provide dates and results of COVID-19 diagnostic testing (swab or other)' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 01:56:30
User opened query 'PV Query: Please indicate any risk factors the subject had for the development of COVID-19, (advanced age, obesity, underlying cardiac conditions, congregate living, recent exposure, cancer, immunosuppression, hypertension, diabetes, asthma, other respiratory conditions, stressful situations, etc).' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 01:56:01
User opened query 'PV Query: Please report if the subject had any known exposure to COVID-19' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 01:55:39
User opened query 'PV Query: Please assess if acute respiratory failure, acute kidney injury, acute respiratory distress syndrome, multifocal pneumonia met criteria for SAE/AE reporting?' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 01:53:54
User opened query 'PV Query: Please send a hospital discharge summary and or pertinent consult notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 01:52:22
User closed query 'PV Urgent Query: Please send a hospital discharge summary and or pertinent consult notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 17:30:55
User closed query 'Urgent PV Query: Has COVID-19 testing been repeated at any lab? Please provide dates and results of COVID-19 diagnostic testing (swab or other).' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 17:30:52

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Audit	User	Time (GMT)
User closed query 'Urgent PV Query: Describe signs and symptoms, and clinical course of the event.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:38:16
User closed query 'Urgent PV Query: Please provide relevant medical history, with onset date(s), severity, treatment and relevant details' (Site from Safety).		20 Nov 2020 22:38:06
User closed query 'Urgent PV Query: Please indicate any risk factors the subject had for the development of COVID-19, (advanced age, obesity, underlying cardiac conditions, congregate living, recent exposure, cancer, immunosuppression, hypertension, diabetes, asthma, other respiratory conditions, stressful situations, etc).' ' (Site from Safety).		20 Nov 2020 22:37:46
Query 'PV Urgent Query: Please send a hospital discharge summary and or pertinent consult notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'subject is currently still in the hospital' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:56:50
Query 'Urgent PV Query: Has COVID-19 testing been repeated at any lab? Please provide dates and results of COVID-19 diagnostic testing (swab or other).' answered with 'went to pcp 11 nov 2020 tested and came back positive and started on steroids and then came for illness visit and was tested at study site 12 nov 2020' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:56:15
Query 'Urgent PV Query: Describe signs and symptoms, and clinical course of the event.' answered with '08 nov 2020 symptoms started ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:55:10
Query 'Urgent PV Query: Please provide relevant medical history, with onset date(s), severity, treatment and relevant details' answered with 'in narrative' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:53:05

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Audit	User	Time (GMT)
Query 'Urgent PV Query: Please indicate any risk factors the subject had for the development of COVID-19, (advanced age, obesity, underlying cardiac conditions, congregate living, recent exposure, cancer, immunosuppression, hypertension, diabetes, asthma, other respiratory conditions, stressful situations, etc). ' answered with 'obesity' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:52:34
Query 'Urgent PV Query: Please provide rationale for seriousness assessment of Life-threatening for event COVID19 -LIKE ILLNESS.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 20:01:15
Query 'Urgent PV Query: Please describe medical indication for hospitalization.' canceled (Site from Safety).		20 Nov 2020 20:00:37
Query 'PV Urgent Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).		20 Nov 2020 19:59:54
User opened query 'PV Urgent Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:44:03
Query 'Urgent PV Query: Please report the treatment received by the subject, including hospitalization and any procedures.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:43:51
Query 'Urgent PV Query: Please provide rationale for assessing the event COVID19 LIKE ILLNESS as possible related to both mRNA-1273 and Study procedure.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:42:11

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Audit	User	Time (GMT)
User opened query 'PV Urgent Query: Please send a hospital discharge summary and or pertinent consult notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:41:06
Query 'Urgent PV Query: Please provide results of pertinent consult notes if any or discharge summary when available and applicable.' canceled (Site from Safety).		20 Nov 2020 19:40:55
User opened query 'Urgent PV Query: Has COVID-19 testing been repeated at any lab? Please provide dates and results of COVID-19 diagnostic testing (swab or other).' (Site from Safety).		20 Nov 2020 19:39:54
Query 'Urgent PV Query: Subject tested negative for COVID-19 on 12-Nov-2020. Has COVID-19 testing been repeated at any lab? Please provide dates and results of COVID-19 diagnostic testing (swab or other)' canceled (Site from Safety).		20 Nov 2020 19:39:39
User opened query 'Urgent PV Query: Please report the treatment received by the subject, including hospitalization and any procedures.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:29:27
User opened query 'Urgent PV Query: Describe signs and symptoms, and clinical course of the event.' (Site from Safety).		20 Nov 2020 19:29:00
User opened query 'Urgent PV Query: Please provide results of pertinent consult notes if any or discharge summary when available and applicable.' (Site from Safety).		20 Nov 2020 19:28:47
User opened query 'Urgent PV Query: Please provide relevant medical history, with onset date(s), severity, treatment and relevant details' (Site from Safety).		20 Nov 2020 19:28:27
User opened query 'Urgent PV Query: Please indicate any risk factors the subject had for the development of COVID-19, (advanced age, obesity, underlying cardiac conditions, congregate living, recent exposure, cancer, immunosuppression, hypertension, diabetes, asthma, other respiratory conditions, stressful situations, etc). ' (Site from Safety).		20 Nov 2020 19:28:14

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Audit	User	Time (GMT)
User opened query 'Urgent PV Query: Please describe medical indication for hospitalization.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:27:52
User opened query 'Urgent PV Query: Subject tested negative for COVID-19 on 12-Nov-2020. Has COVID-19 testing been repeated at any lab? Please provide dates and results of COVID-19 diagnostic testing (swab or other)' (Site from Safety).		20 Nov 2020 19:27:40
User opened query 'Urgent PV Query: Please provide rationale for assessing the event COVID19 LIKE ILLNESS as possible related to both mRNA-1273 and Study procedure.' (Site from Safety).		20 Nov 2020 19:27:30
User opened query 'Urgent PV Query: Please provide rationale for seriousness assessment of Life-threatening for event COVID19 -LIKE ILLNESS.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 19:27:15
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:45:44
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Nov 2020 21:51:16
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	19 Nov 2020 21:51:16
User entered 'Pct called and reported O2 saturation in the 80s%. Directed patient to emergency department for sustained hypoxia. Found to be 78% on RA. Patient started on Bipap with O2 75% and transferred to ICU. Dx with acute respiratory failure, AKI, ARDs, and multifocal pneumonia.	Whitney West (b) (4)	19 Nov 2020 21:51:16
Was started on albuterol sulfate, deltasone, ceftriaxone, azithromycin, dexamethasone, exnoxaparin, remdesivir upon admission. Requesting further information.' reason for change: New Information		
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Nov 2020 23:24:49
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 23:24:49

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	16 Nov 2020 23:24:49

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	19 Nov 2020 21:51:16
User entered '0'	System	16 Nov 2020 23:24:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 17:14:08
User entered 'USA-US070-2020-mRNA-1273-P301000019'	(b) (4), (b) (6)	15 Dec 2020 17:13:55
DataPoint activated with code reason code Data required.	Whitney West (b) (4) (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4) (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 11:17:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 11:17:51
Data point term sent to Coder	System	14 Dec 2020 20:25:14
User entered 'Multifocal Pneumonia'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'No (N)'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '16 Nov 2020'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:45:50
DataPoint Un-verified.	Whitney West (b) (4)	15 Feb 2021 17:47:33
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	15 Feb 2021 17:47:33
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:45:52
DataPoint Un-verified.	Whitney West (b) (4)	15 Feb 2021 17:47:33
User entered '11 Feb 2021' reason for change: New Information	Whitney West (b) (4)	15 Feb 2021 17:47:33
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).		27 Apr 2021 23:26:25
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:29:03
User entered empty.	System	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Grade 4 (Grade 4)'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '0'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'l'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	25 Dec 2020 07:17:30
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
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 'This has prolongation of existing hospitalization. He is admitted with ICU admission. He has not been discharged. There is no discharge date. ' (Site from System).	Whitney West (b) (4)	14 Dec 2020 20:48:41
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	14 Dec 2020 20:24:10
User entered '1'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '16 Nov 2020'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:45:58
User closed query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).		08 Feb 2021 12:58:26
Query 'PV Query: Please provide the hospital discharge date when available' answered with 'Updated.' (Site from Safety).	Whitney West (b) (4)	06 Feb 2021 23:05:28
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	06 Feb 2021 23:05:17
User entered '25 Jan 2021' reason for change: New Information	Whitney West (b) (4)	06 Feb 2021 23:03:58
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:40:22
User opened query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).		18 Dec 2020 16:28:28
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '28'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '0'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '0'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '0'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:18:59

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 20:51:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Dec 2020 20:51:20
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Whitney West (b) (4)	14 Dec 2020 20:51:20
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 20:24:10
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		14 Dec 2020 20:51:03
User entered '0' reason for change: Data Entry Error Whitney West	(b) (4)	14 Dec 2020 20:51:03
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4) System	14 Dec 2020 20:24:10
User entered '1'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	(b) (4) Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	(b) (4) Whitney West (b) (4)	06 Dec 2020 00:43:08

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'l'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'l'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:46:05
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Whitney West (b) (4)	15 Feb 2021 17:47:33
DataPoint Un-verified.	Whitney West (b) (4)	06 Feb 2021 23:05:58
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Whitney West (b) (4)	06 Feb 2021 23:05:58
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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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)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:46:10
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:52:55
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'New baseline. ' (Site from Safety).	Whitney West (b) (4)	15 Feb 2021 17:47:49
User entered 'Participant returned home. Remains on 1L/NC at rest, 3L/NC with activity, and 2L/NC HS.' reason for change: Data Entry Error	Whitney West (b) (4)	15 Feb 2021 17:47:33
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:40:28
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:28:02
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:46:14

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'ADMITTED FOR ARDS D/T COVID-19 VIRUS. DIAGNOSED WITH COVID PNEUMONIA IN MID-NOVEMBER 2020 AND SUBSEQUENTLY DEVELOPED RESPIRATORY FAILURE D/T ASSOCIATED ARDS AND REQUIRED EMERGENT INTUBATION AT THE END OF THE MONTH DUE TO SEVERE HYPOXIA. DESPITE MAXIMAL VENT SETTINGS, THE PATIENT COULD NOT MAINTAIN ADEQUATE OXYGEN SATURATION AND WAS SENT TO A REGIONAL HOSPITAL AT THE BEGINNING OF DECEMBER FOR EVALUATION FOR VV ECMO. PARTICIPANT WAS CANNULATED AND EVENTUALLY REQUIRED TRACHEOSTOMY D/T PROLONGED VENTILATION REQUIREMENTS. ECMO WAS DECANNULATED 01JAN2021. HOSPITAL COURSE WAS COMPLICATED BY VRE BACTEREMIA, TRACH SITE BLEEDING, EPISTAXIS AND THROMBOCYTOPENIA WITH BOTH HEME/ONC AND ID ON BOARD. PARTICIPANT SEROTONIN RELEASE ASSAY IS NEGATIVE MAKING HIT LESS LIKELY. PARTICIPANT COMPLETED ANTIBIOTICS AND WAS STARTED ON PREDNISONE WITH CONCERN CAP. ON PREDNISONE TAPER WITH BACTRIM ON BOARD. DISMISSED TO LOCAL REHAB FACILITY WHERE HE HAD HEMORRHAGING FROM HIS TRACHEA AND WAS TRANSFERRED BACK FOR EVALUATION. HEMORRHAGE RESOLVED WITHOUT INTERVENTION, TRACHEOSTOMY DECANNULATION 25JAN2021. TUBE FEEDINGS STOPPED AS PO RESUMED. TRANSFERRED BACK TO REHAB. SUPPLEMENTAL 1-3L/NC WITH ACTIVITY. Discharged to home 11FEB2021.' reason for change: New Information	Whitney West (b) (4)	15 Feb 2021 17:47:33
DataPoint Un-verified.	Whitney West (b) (4)	06 Feb 2021 23:38:32

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Audit	User	Time (GMT)
User entered 'Admitted for ARDS d/t COVID-19 virus. Diagnosed with Covid pneumonia in mid-November 2020 and subsequently developed respiratory failure d/t associated ARDS and required emergent intubation at the end of the month due to severe hypoxia. Despite maximal vent settings, the patient could not maintain adequate oxygen saturation and was sent to a regional hospital at the beginning of December for evaluation for VV ECMO. Participant was cannulated and eventually required tracheostomy d/t prlonged ventilation requirements. ECMO was decannulated 01JAN2021. Hospital course was complicated by VRE bacteremia, trach site bleeding, epistaxis and thrombocytopenia with both heme/onc and ID on board. Participant serotonin release assay is negative making HIT less likely. Participant completed antibiotics and was started on prednisone with concern CAP. On prednisone taper with Bactrim on board. Dismissed to local rehab facility where he had hemorrhaging from his trachea and was transferred back for evaluation. Hemorrhage resolved without intervention, tracheostomy decannulation 25JAN2021. Tube feedings stopped as PO resumed. Transferred back to rehab. Supplemental 1-3L/NC with activity, likely discharge to home 11FEB2021.' reason for change: New Information DataPoint Verified.	Whitney West (b) (4) (b) (4)	06 Feb 2021 23:38:32
	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Dec 2020 20:53:05
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	14 Dec 2020 20:53:05

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Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User entered '16NOV2020- PCT CALLED AND REPORT 02 IN 80S%. DIRECTED TO ER FOR SUSTAINED HYPOXIA 78% ON ROOM AIR. PCT ESCALATED TO BIPAP WITH 02 75% AND TRANSFERRED TO ICU. CHEST X-RAY-BILATERAL PNEUMONIA, CT ANGIO R/O LARGE PE, D-DIMER NEGATIVESTARTED ON ALBUTEROL SULFATE, DELTASONE, CEFTRIAZONE, AZITHROMYCIN, DEXAMETHASONE, ENOXAPARIN, REMDESEVIR STARTED UPON ADMISSION. LAB REVEALS CRT 1.64- ACUTE KIDNEY INJURY- HYDRATION STARTED THEN STOPPED. BEGINS LORAZEPAM FOR ANXIETY SECONDARY TO OXYGEN MASKS. CONVALESCENT PLASMA. LASIX FOR EDEMA. 23NOV BIPAP 100 FIO2. BLOOD AND SPUTUM CULTURES NEGATIVE. ELEVATED DDIMER- KIDNEY/LUNG FUNCTION R/O SCANS. INCREASED ENOXAPARIN. EKG FOR STARTING RUXOLITINIB CLINICAL DRUG INITIATION ON 24NOV2020. CONTINUED DETERIORATION. DEXMEDETOMIDINE INFUSION STARTED 26NOV- STILL SYMPTOMATIC AND FULL BIPAP SUPPORT. STARTED SUPPLEMENTS FOR IMMUNE SUPPORT ON 27NOV, INCREASED STEROIDS. 28NOV EMERGENT INTUBATION AFTER SEVERE COUGHING SPELL C EXTREME RESP DISTRESS. TACHYPNEIC, TACHYCARDIC, AND CYANOTIC APPEARANCE. ID FOLLOWING. INHALED EPOPROSTENOL. OG, ETT, RIGHT RAD ART LINE. MIDLINE INSERTED. EPOPROSTENOL, FENTANYL, PROPOFOL INITIATED. VASOPRESSORS STARTED AND STOPPED. ACUTE KIDNEY INJURY RESOLVED. SPUTUM CULTURES NEGATIVE AGAIN. NEED ESCALATION TO ECMO, TRANSFERRED TO REGIONAL HOSPITAL 01DEC2020. TTE, BRONCH, DOPPLERS TO PREP FOR ECMO PLACEMENT.	Whitney West (b) (4)	14 Dec 2020 20:53:05

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[Narrative](#)

Audit	User	Time (GMT)
LASIX CONTINUED. TUBE FEEDINGS WITH Q6 INSULIN. NICARDIPINE STARTED AND STOPPED. VV ECMO PLACEMENT 02DEC2020. PCR ON 02DEC2020 STILL POSITIVE FOR COVID-19. PER FAMILY REPORT, PARTICIPANT RECEIVED TRACHEOSTOMY ON 10DEC2020, STILL RECEIVING TREATMENT, MEDICAL TEAM ESTIMATES MULTIPLE WEEKS BEFORE BEGINNING TO TRY TO WEAN SEDATION ON THE PARTICIPANT. STILL ON ECMO AND VENT.'		
reason for change: Data Entry Error User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Dec 2020 20:24:10
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (2)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	14 Dec 2020 20:24:10
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	07 Dec 2020 20:53:47
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	06 Dec 2020 00:43:08

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
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 kidney injury - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 20:22:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 20:22:50
Data point term sent to Coder	System	14 Dec 2020 20:22:03
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
Data point term sent to Coder	System	08 Dec 2020 21:08:58
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
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 kidney injury - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 20:53:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 20:53:49
Data point term sent to Coder	System	07 Dec 2020 20:52:37
User entered 'Acute kidney injury'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered 'Yes (Y)'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Form: Adverse Events (3)

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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)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:52:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 20:52:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Whitney West (b) (4)	07 Dec 2020 20:52:50
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:52:34
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Form: Adverse Events (3)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered '16 Nov 2020'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:52:34

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered empty.	System	07 Dec 2020 20:52:34

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Form: Adverse Events (3)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:46:27
DataPoint Un-verified.	Whitney West (b) (4)	16 Jan 2021 15:39:16
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	16 Jan 2021 15:39:16
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered 'Yes (Y)'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:46:29
DataPoint Un-verified.	Whitney West (b) (4)	16 Jan 2021 15:39:16
User entered '30 Nov 2020' reason for change: Data Entry Error	Whitney West (b) (4)	16 Jan 2021 15:39:16
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Folder: Adverse Events

Form: Adverse Events (3)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Form: Adverse Events (3)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered empty.	System	07 Dec 2020 20:52:34

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered '0'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered '0'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered '0'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Folder: Adverse Events

Form: Adverse Events (3)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered '0'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered '0'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered '0'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered '0'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered 'I'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered '0'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:46:35
DataPoint Un-verified.	Whitney West (b) (4)	16 Jan 2021 15:39:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Whitney West (b) (4)	16 Jan 2021 15:39:16
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:46:39
User closed query 'Per DM CLR: SAE Narrative = CREATININE LEVELS: 16NOV2020: 1.64 17NOV2020: 1.42 25NOV2020: 1.38 26NOV2020: 1.21 28NOV2020: 0.93. However, these were not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 07:32:31
Query 'Per DM CLR: SAE Narrative = CREATININE LEVELS: 16NOV2020: 1.64 17NOV2020: 1.42 25NOV2020: 1.38 26NOV2020: 1.21 28NOV2020: 0.93. However, these were not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Have been instructed not to include procedures if they are diagnostic only.' (Site from DM).	Whitney West (b) (4)	06 Feb 2021 23:39:37
User opened query 'Per DM CLR: SAE Narrative = CREATININE LEVELS: 16NOV2020: 1.64 17NOV2020: 1.42 25NOV2020: 1.38 26NOV2020: 1.21 28NOV2020: 0.93. However, these were not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Jan 2021 12:35:30

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT WAS ADMITTED TO THE HOSPITAL ON 16NOV2020 FOR ACUTE HYPOXIC RESPIRATORY FAILURE SECONDARY TO ARDS FROM COVID-19. AKI WAS FOUND INCIDENTALLY VIA LABORATORY RESULTS. CREATININE 16NOV2020 WAS 1.64 AND 17NOV2020 WAS 1.42. PARTICIPANT WAS TREATED WITH GENTLE HYDRATION X 48 HOURS FOLLOWED BY FUROSEMIDE DAILY. CREATININE LEVELS: 16NOV2020: 1.64 17NOV2020: 1.42 25NOV2020: 1.38 26NOV2020: 1.21 28NOV2020: 0.93 30NOV2020: NEPHROLOGY CONSIDERS AKI RESOLVED AND SIGNS OFF.' reason for change: New Information DataPoint Un-verified.	Whitney West (b) (4) (b) (4)	16 Jan 2021 15:48:30
User entered 'PARTICIPANT WAS ADMITTED TO THE HOSPITAL ON 16NOV2020 FOR ACUTE HYPOXIC RESPIRATORY FAILURE SECONDARY TO ARDS FROM COVID-19. AKI WAS FOUND INCIDENTALLY VIA LABORATORY RESULTS. CREATININE 16NOV2020 WAS 1.64 AND 17NOV2020 WAS 1.42. Participant was treated with gentle hydration x 48 hours followed by furosemide daily. Creatinine levels: 16NOV2020: 1.64 17NOV2020: 1.42 25NOV2020: 1.38 26NOV2020: 1.21 27NOV2020: 28NOV2020: 0.93 29NOV2020: Nephrology considers AKI resolved and signs off.' reason for change: New Information DataPoint Verified.	Whitney West (b) (4) (b) (4) (b) (4), (b) (6)	16 Jan 2021 15:39:16
DataPoint activated with code reason code Data required.	Whitney West (b) (4) (b) (4)	14 Dec 2020 20:21:46

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered 'Participant was admitted to the hospital on 16NOV2020 for acute hypoxic respiratory failure secondary to ARDS from Covid-19. AKI was found incidentally via laboratory results. Creatinine 16NOV2020 was 1.64 and 17NOV2020 was 1.42.'	Whitney West (b) (4)	07 Dec 2020 20:52:34

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Form: Adverse Events (3)

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Dec 2020 21:08:51
User entered '0'	Whitney West (b) (4)	07 Dec 2020 20:52:34
	System	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51
User entered '1'	System	07 Dec 2020 20:52:34

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Folder: Adverse Events

Form: Adverse Events (3)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:17:34
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	14 Dec 2020 20:21:46
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	08 Dec 2020 21:08:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
Reviewed for Safety.		15 Dec 2020 17:17:59
User entered 'USA-US070-2020-mRNA-1273-P301000019'		15 Dec 2020 17:17:53

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 20:55:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 20:55:53
Data point term sent to Coder	System	14 Dec 2020 20:55:07
User entered 'Acute Respiratory Failure'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'No (N)'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '16 Nov 2020'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:46:49
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	06 Feb 2021 23:41:30
DataPoint Un-verified.	Whitney West (b) (4)	06 Feb 2021 23:41:30
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	06 Feb 2021 23:41:30
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	06 Feb 2021 23:41:13
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:46:53
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	06 Feb 2021 23:41:13
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	06 Feb 2021 23:41:13
DataPoint Un-verified.	Whitney West (b) (4)	06 Feb 2021 23:41:13
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	06 Feb 2021 23:41:13
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	06 Feb 2021 23:40:49
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:54:56

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).		27 Apr 2021 23:27:01
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:21:06
User entered empty.	System	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Grade 4 (Grade 4)'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '0'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'l'	Whitney West (b) (4)	14 Dec 2020 20:54:56

US3272026

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	25 Dec 2020 07:18:07
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
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 'Not discharged yet. ' (Site from System).	Whitney West (b) (4)	14 Dec 2020 20:55:48
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	14 Dec 2020 20:54:56
User entered 'I'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '16 Nov 2020'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:46:59
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).		08 Feb 2021 12:57:50
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	06 Feb 2021 23:40:49
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with 'Discharged 22JAN2021' (Site from Safety).	Whitney West (b) (4)	05 Feb 2021 21:55:04
User entered '22 Jan 2021' reason for change: New Information	Whitney West (b) (4)	05 Feb 2021 21:54:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:39:40
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).		18 Dec 2020 16:20:38
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '28'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '0'	Whitney West (b) (4)	14 Dec 2020 20:54:56

US3272026

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '0'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '0'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '0'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'l'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'l'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:47:05
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 22:00:54
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 12:57:46
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Updated.' (Site from Safety).	Whitney West (b) (4)	06 Feb 2021 23:41:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Whitney West (b) (4)	06 Feb 2021 23:40:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Whitney West (b) (4)	05 Feb 2021 21:54:17
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:39:51
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:21:38
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Whitney West (b) (4)	14 Dec 2020 20:54:56

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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)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:47:08
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	17 Feb 2021 22:01:48
DataPoint Un-verified.	Whitney West (b) (4)	17 Feb 2021 22:01:48
User entered 'Increased O2 needs: Baseline- 1L/NC HS- 2L/NC Activity- 3L/NC' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 22:01:48
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	17 Feb 2021 22:00:54
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:47:12

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'ADMITTED FOR ARDS D/T COVID-19 VIRUS. DIAGNOSED WITH COVID PNEUMONIA IN MID-NOVEMBER 2020 AND SUBSEQUENTLY DEVELOPED RESPIRATORY FAILURE D/T ASSOCIATED ARDS AND REQUIRED EMERGENT INTUBATION AT THE END OF THE MONTH DUE TO SEVERE HYPOXIA. DESPITE MAXIMAL VENT SETTINGS, THE PATIENT COULD NOT MAINTAIN ADEQUATE OXYGEN SATURATION AND WAS SENT TO A REGIONAL HOSPITAL AT THE BEGINNING OF DECEMBER FOR EVALUATION FOR VV ECMO. PARTICIPANT WAS CANNULATED AND EVENTUALLY REQUIRED TRACHEOSTOMY D/T PROLONGED VENTILATION REQUIREMENTS. ECMO WAS DECANNULATED 01JAN2021. HOSPITAL COURSE WAS COMPLICATED BY VRE BACTEREMIA, TRACH SITE BLEEDING, EPISTAXIS AND THROMBOCYTOPENIA WITH BOTH HEME/ONC AND ID ON BOARD. PARTICIPANT SEROTONIN RELEASE ASSAY IS NEGATIVE MAKING HIT LESS LIKELY. PARTICIPANT COMPLETED ANTIBIOTICS AND WAS STARTED ON PREDNISONE WITH CONCERN CAP. ON PREDNISONE TAPER WITH BACTRIM ON BOARD. DISMISSED TO LOCAL REHAB FACILITY WHERE HE HAD HEMORRHAGING FROM HIS TRACHEA AND WAS TRANSFERRED BACK FOR EVALUATION. HEMORRHAGE RESOLVED WITHOUT INTERVENTION, TRACHEOSTOMY DECANNULATION 25JAN2021. TUBE FEEDINGS STOPPED AS PO RESUMED. Discharged home 12FEB2021. Increased O2 needs, 1L/NC baseline, 2L/NC HS, 3L/NC with activity.'	Whitney West (b) (4)	17 Feb 2021 22:00:54
reason for change: New Information		

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Admitted for ARDS d/t COVID-19 virus. Diagnosed with Covid pneumonia in mid-November 2020 and subsequently developed respiratory failure d/t associated ARDS and required emergent intubation at the end of the month due to severe hypoxia. Despite maximal vent settings, the patient could not maintain adequate oxygen saturation and was sent to a regional hospital at the beginning of December for evaluation for VV ECMO. Participant was cannulated and eventually required tracheostomy d/t prlonged ventilation requirements. ECMO was decannulated 01JAN2021. Hospital course was complicated by VRE bacteremia, trach site bleeding, epistaxis and thrombocytopenia with both heme/onc and ID on board. Participant serotonin release assay is negative making HIT less likely. Participant completed antibiotics and was started on prednisone with concern CAP. On prednisone taper with Bactrim on board. Dismissed to local rehab facility where he had hemorrhaging from his trachea and was transferred back for evaluation. Hemorrhage resolved without intervention, tracheostomy decannulation 25JAN2021. Tube feedings stopped as PO resumed. Transferred back to rehab. Supplemental 1-3L/NC with activity, likely discharge to home 11FEB2021.'	Whitney West (b) (4)	06 Feb 2021 23:40:10
reason for change: New Information	(b) (4), (b) (6)	04 Feb 2021 16:39:59
User closed query 'Consider updating the narrative to include the diagnosis of ARDS.' (Site from CRA).		
User closed query 'Per DM CLR: Narrative indicates that the subject had Chest Xray, CT Angiogram, Tracheostomy and EKG. However, there is no corresponding Concomitant Procedures record that match the information. Please update to record accordingly. Otherwise, clarify.' (Site from DM).		21 Jan 2021 09:34:40
User closed query 'Per DM CLR: Narrative indicates that AKI has resolved. However, AE #3 (Acute Kidney Injury) is still listed as ongoing. Please reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 20:36:16

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that the subject had Chest Xray, CT Angiogram, Tracheostomy and EKG. However, there is no corresponding Concomitant Procedures record that match the information. Please update to record accordingly. Otherwise, clarify.' answered with 'We were previously told to not include Chest xray, CT angiogram, and EKGs as these were not procedures to treat, but were instead diagnostic tools. These were previously listed as procedures and were inactivated in response to this previous directive- please clarify and we can reactivate those entries. ' (Site from DM).	Whitney West (b) (4)	16 Jan 2021 15:43:05
Query 'Per DM CLR: Narrative indicates that AKI has resolved. However, AE #3 (Acute Kidney Injury) is still listed as ongoing. Please reconcile and update accordingly. Otherwise, clarify.' answered with 'AKI was updated. ' (Site from DM).	Whitney West (b) (4)	16 Jan 2021 15:28:58
User opened query 'Per DM CLR: Narrative indicates that AKI has resolved. However, AE #3 (Acute Kidney Injury) is still listed as ongoing. Please reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 19:29:44
User opened query 'Per DM CLR: Narrative indicates that the subject had Chest Xray, CT Angiogram, Tracheostomy and EKG. However, there is no corresponding Concomitant Procedures record that match the information. Please update to record accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 19:29:34
Query 'Consider updating the narrative to include the diagnosis of ARDS.' answered with 'Added. Diagnosed with ARDS on admission- added to admission date. ' (Site from CRA).	Whitney West (b) (4)	19 Dec 2020 23:53:11
DataPoint Un-verified.	Whitney West (b) (4)	19 Dec 2020 23:52:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
User entered '16NOV2020- PCT CALLED AND REPORT 02 IN 80S%. DIRECTED TO ER FOR SUSTAINED HYPOXIA 78% ON ROOM AIR. PCT ESCALATED TO BIPAP WITH 02 75% AND TRANSFERRED TO ICU. CHEST X-RAY-BILATERAL PNEUMONIA, CT ANGIO R/O LARGE PE, D-DIMER NEGATIVESTARTED ON ALBUTEROL SULFATE, DELTASONE, CEFTRIAZONE, AZITHROMYCIN, DEXAMETHASONE, ENOXAPARIN, REMDESEVIR STARTED UPON ADMISSION. Dx of ARDS. LAB REVEALS CRT 1.64- ACUTE KIDNEY INJURY- HYDRATION STARTED THEN STOPPED. BEGINS LORAZEPAM FOR ANXIETY SECONDARY TO OXYGEN MASKS. CONVALESCENT PLASMA. LASIX FOR EDEMA. 23NOV BIPAP 100 FIO2. BLOOD AND SPUTUM CULTURES NEGATIVE. ELEVATED DDIMER- KIDNEY/LUNG FUNCTION R/O SCANS. INCREASED ENOXAPARIN. EKG FOR STARTING RUXOLITINIB CLINICAL DRUG INITIATION ON 24NOV2020. CONTINUED DETERIORATION. DEXMEDETOMIDINE INFUSION STARTED 26NOV- STILL SYMPTOMATIC AND FULL BIPAP SUPPORT. STARTED SUPPLEMENTS FOR IMMUNE SUPPORT ON 27NOV, INCREASED STEROIDS. 28NOV EMERGENT INTUBATION AFTER SEVERE COUGHING SPELL C EXTREME RESP DISTRESS. TACHYPNEIC, TACHYCARDIC, AND CYANOTIC APPEARANCE. ID FOLLOWING. INHALED EPOPROSTENOL. OG, ETT, RIGHT RAD ART LINE. MIDLINE INSERTED. EPOPROSTENOL, FENTANYL, PROPOFOL INITIATED. VASOPRESSORS STARTED AND STOPPED. ACUTE KIDNEY INJURY RESOLVED. SPUTUM CULTURES NEGATIVE AGAIN. NEED ESCALATION TO ECMO, TRANSFERRED TO REGIONAL HOSPITAL 01DEC2020. TTE, BRONCH, DOPPLERS TO PREP FOR ECMO PLACEMENT.	Whitney West (b) (4)	19 Dec 2020 23:52:42

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
LASIX CONTINUED. TUBE FEEDINGS WITH Q6 INSULIN. NICARDIPINE STARTED AND STOPPED. VV ECMO PLACEMENT 02DEC2020. PCR ON 02DEC2020 STILL POSITIVE FOR COVID-19. PER FAMILY REPORT, PARTICIPANT RECEIVED TRACHEOSTOMY ON 10DEC2020, STILL RECEIVING TREATMENT, MEDICAL TEAM ESTIMATES MULTIPLE WEEKS BEFORE BEGINNING TO TRY TO WEAN SEDATION ON THE PARTICIPANT. STILL ON ECMO AND VENT.'		
reason for change: Data Entry Error User opened query 'Consider updating the narrative to include the diagnosis of ARDS.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:45:27
		17 Dec 2020 17:37:52

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
User entered '16NOV2020- PCT CALLED AND REPORT 02 IN 80S%. DIRECTED TO ER FOR SUSTAINED HYPOXIA 78% ON ROOM AIR. PCT ESCALATED TO BIPAP WITH 02 75% AND TRANSFERRED TO ICU. CHEST X-RAY-BILATERAL PNEUMONIA, CT ANGIO R/O LARGE PE, D-DIMER NEGATIVE STARTED ON ALBUTEROL SULFATE, DELTASONE, CEFTRIAZONE, AZITHROMYCIN, DEXAMETHASONE, ENOXAPARIN, REMDESEVIR STARTED UPON ADMISSION. LAB REVEALS CRT 1.64- ACUTE KIDNEY INJURY- HYDRATION STARTED THEN STOPPED. BEGINS LORAZEPAM FOR ANXIETY SECONDARY TO OXYGEN MASKS. CONVALESCENT PLASMA. LASIX FOR EDEMA. 23NOV BIPAP 100 FIO2. BLOOD AND SPUTUM CULTURES NEGATIVE. ELEVATED DDIMER- KIDNEY/LUNG FUNCTION R/O SCANS. INCREASED ENOXAPARIN. EKG FOR STARTING RUXOLITINIB CLINICAL DRUG INITIATION ON 24NOV2020. CONTINUED DETERIORATION. DEXMEDETOMIDINE INFUSION STARTED 26NOV- STILL SYMPTOMATIC AND FULL BIPAP SUPPORT. STARTED SUPPLEMENTS FOR IMMUNE SUPPORT ON 27NOV, INCREASED STEROIDS. 28NOV EMERGENT INTUBATION AFTER SEVERE COUGHING SPELL C EXTREME RESP DISTRESS. TACHYPNEIC, TACHYCARDIC, AND CYANOTIC APPEARANCE. ID FOLLOWING. INHALED EPOPROSTENOL. OG, ETT, RIGHT RAD ART LINE. MIDLINE INSERTED. EPOPROSTENOL, FENTANYL, PROPOFOL INITIATED. VASOPRESSORS STARTED AND STOPPED. ACUTE KIDNEY INJURY RESOLVED. SPUTUM CULTURES NEGATIVE AGAIN. NEED ESCALATION TO ECMO, TRANSFERRED TO REGIONAL HOSPITAL 01DEC2020. TTE, BRONCH, DOPPLERS TO PREP FOR ECMO PLACEMENT.	Whitney West (b) (4)	14 Dec 2020 20:54:56

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
LASIX CONTINUED. TUBE FEEDINGS WITH Q6 INSULIN. NICARDIPINE STARTED AND STOPPED. VV ECMO PLACEMENT 02DEC2020. PCR ON 02DEC2020 STILL POSITIVE FOR COVID-19. PER FAMILY REPORT, PARTICIPANT RECEIVED TRACHEOSTOMY ON 10DEC2020, STILL RECEIVING TREATMENT, MEDICAL TEAM ESTIMATES MULTIPLE WEEKS BEFORE BEGINNING TO TRY TO WEAN SEDATION ON THE PARTICIPANT. STILL ON ECMO AND VENT.'		

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	14 Dec 2020 20:54:56

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered 'I'	System	14 Dec 2020 20:54:56

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Form: Adverse Events (4)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	14 Dec 2020 20:54:56

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Folder: Adverse Events

Form: Adverse Events (5)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
Reviewed for Safety.		15 Dec 2020 17:19:38
User entered 'USA-US070-2020-mRNA-1273-P301000019'		15 Dec 2020 17:18:44

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Folder: Adverse Events

Form: Adverse Events (5)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User coded data point as SOC: Immune system disorders, HLG: Immune disorders NEC, HLT: Immune and associated conditions NEC, PT: Cytokine storm, LLT: Cytokine storm - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 20:58:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 20:58:47
Data point term sent to Coder	System	14 Dec 2020 20:58:09
User entered 'Cytokine Storm'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 20:57:37

US3272026

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'No (N)'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:47:23
User closed query 'Per CDM: Please verify indication is noted as 'Cytokine Strom', However Is this event a confirmed diagnosis of Symptomatic Covid-19? is recorded as "Yes". Please review and update accordingly, Else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 13:02:50
Query 'Per CDM: Please verify indication is noted as 'Cytokine Strom', However Is this event a confirmed diagnosis of Symptomatic Covid-19? is recorded as "Yes". Please review and update accordingly, Else clarify.' answered with 'Updated per query. ' (Site from DM).	Whitney West (b) (4)	06 Feb 2021 23:43:21
User entered 'No (N)' reason for change: Per Query Resolution	Whitney West (b) (4)	06 Feb 2021 23:42:58
DataPoint Un-verified.	(b) (4), (b) (6)	04 Feb 2021 16:39:18
User opened query 'Per CDM: Please verify indication is noted as 'Cytokine Strom', However Is this event a confirmed diagnosis of Symptomatic Covid-19? is recorded as "Yes". Please review and update accordingly, Else clarify.' (Site from DM).		04 Feb 2021 09:32:58
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '28 Nov 2020'	Whitney West (b) (4)	14 Dec 2020 20:57:37

US3272026

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:47:27
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	06 Feb 2021 23:44:34
DataPoint Un-verified.	Whitney West (b) (4)	06 Feb 2021 23:44:34
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	06 Feb 2021 23:44:34
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	06 Feb 2021 23:44:20
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:47:29
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	06 Feb 2021 23:44:20
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	06 Feb 2021 23:44:20
DataPoint Un-verified.	Whitney West (b) (4)	06 Feb 2021 23:44:20
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	06 Feb 2021 23:44:20
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	06 Feb 2021 23:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).		27 Apr 2021 23:27:39
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:18:16
User entered empty.	System	14 Dec 2020 20:57:37

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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)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Grade 4 (Grade 4)'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '0'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'l'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	25 Dec 2020 07:18:28
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
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 'Not discharged. ' (Site from System).	Whitney West (b) (4)	14 Dec 2020 20:58:32
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	14 Dec 2020 20:57:37
User entered 'I'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '16 Nov 2020'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:47:34
User closed query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 18:48:19
Query 'PV Query: Please provide the hospital discharge date when available' answered with 'Participant discharged from the hospital to rehab facility. Records are pending- details are from secondary reports. ' (Site from Safety).	Whitney West (b) (4)	28 Jan 2021 20:40:38
DataPoint Un-verified.	Whitney West (b) (4)	28 Jan 2021 20:39:59
User entered '28 Jan 2021' reason for change: Data Entry Error	Whitney West (b) (4)	28 Jan 2021 20:39:59
User opened query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:16:59
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Yes (Y)'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '28'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '0'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '0'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '0'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '0'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:54:37
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'Will add all diagnoses to all meds per query instruction. ' (Site from DM).	Whitney West (b) (4)	16 Feb 2021 16:15:09
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:33:25
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered '1'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'l'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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Form: Adverse Events (5)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:47:41
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 12:57:20
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Updated.' (Site from Safety).	Whitney West (b) (4)	06 Feb 2021 23:44:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Whitney West (b) (4)	06 Feb 2021 23:43:49
Data Entry Error		
DataPoint Un-verified.	Whitney West (b) (4)	28 Jan 2021 20:39:59
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Whitney West (b) (4)	28 Jan 2021 20:39:59
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:18:43
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Whitney West (b) (4)	14 Dec 2020 20:57:37

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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)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:37:52
User entered empty.	Whitney West (b) (4)	14 Dec 2020 20:57:37

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:47:45

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'ADMITTED FOR ARDS D/T COVID-19 VIRUS. DIAGNOSED WITH COVID PNEUMONIA IN MID-NOVEMBER 2020 AND SUBSEQUENTLY DEVELOPED RESPIRATORY FAILURE D/T ASSOCIATED ARDS AND REQUIRED EMERGENT INTUBATION AT THE END OF THE MONTH DUE TO SEVERE HYPOXIA. DESPITE MAXIMAL VENT SETTINGS, THE PATIENT COULD NOT MAINTAIN ADEQUATE OXYGEN SATURATION AND WAS SENT TO A REGIONAL HOSPITAL AT THE BEGINNING OF DECEMBER FOR EVALUATION FOR VV ECMO. PARTICIPANT WAS CANNULATED AND EVENTUALLY REQUIRED TRACHEOSTOMY D/T PROLONGED VENTILATION REQUIREMENTS. ECMO WAS DECANNULATED 01JAN2021. HOSPITAL COURSE WAS COMPLICATED BY VRE BACTEREMIA, TRACH SITE BLEEDING, EPISTAXIS AND THROMBOCYTOPENIA WITH BOTH HEME/ONC AND ID ON BOARD. PARTICIPANT SEROTONIN RELEASE ASSAY IS NEGATIVE MAKING HIT LESS LIKELY. PARTICIPANT COMPLETED ANTIBIOTICS AND WAS STARTED ON PREDNISONE WITH CONCERN CAP. ON PREDNISONE TAPER WITH BACTRIM ON BOARD. DISMISSED TO LOCAL REHAB FACILITY WHERE HE HAD HEMORRHAGING FROM HIS TRACHEA AND WAS TRANSFERRED BACK FOR EVALUATION. HEMORRHAGE RESOLVED WITHOUT INTERVENTION, TRACHEOSTOMY DECANNULATION 25JAN2021. TUBE FEEDINGS STOPPED AS PO RESUMED. TRANSFERRED BACK TO REHAB. SUPPLEMENTAL 1-3L/NC WITH ACTIVITY, DISCHARGED HOME 11FEB2021.' reason for change: New Information DataPoint Un-verified.	Whitney West (b) (4) (b) (4)	16 Feb 2021 16:13:38
	Whitney West (b) (4) (b) (4)	06 Feb 2021 23:42:58

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Admitted for ARDS d/t COVID-19 virus. Diagnosed with Covid pneumonia in mid-November 2020 and subsequently developed respiratory failure d/t associated ARDS and required emergent intubation at the end of the month due to severe hypoxia. Despite maximal vent settings, the patient could not maintain adequate oxygen saturation and was sent to a regional hospital at the beginning of December for evaluation for VV ECMO. Participant was cannulated and eventually required tracheostomy d/t prlonged ventilation requirements. ECMO was decannulated 01JAN2021. Hospital course was complicated by VRE bacteremia, trach site bleeding, epistaxis and thrombocytopenia with both heme/onc and ID on board. Participant serotonin release assay is negative making HIT less likely. Participant completed antibiotics and was started on prednisone with concern CAP. On prednisone taper with Bactrim on board. Dismissed to local rehab facility where he had hemorrhaging from his trachea and was transferred back for evaluation. Hemorrhage resolved without intervention, tracheostomy decannulation 25JAN2021. Tube feedings stopped as PO resumed. Transferred back to rehab. Supplemental 1-3L/NC with activity, likely discharge to home 11FEB2021.'	Whitney West (b) (4)	06 Feb 2021 23:42:58
reason for change: New Information User closed query 'PV Query:It would be appreciated, if the site provides the rationale of the event term cytokine storm. ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 21:43:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query:It would be appreciated, if the site provides the rationale of the event term cytokine storm. ' answered with 'Two doctors of the treatment team diagnosed participant 2026 with Cytokine Storm on 28-29NOV2020. He has had elevated CRP: CRP: 80.60 from 16NOV2020 CRP: 78.70 from 19NOV2020 (normal 9.00 mg/L) CRP: 22.20 from 21NOV2020 No signs of organ dysfunction other than known lung injuries. He is an active participant still and so there is a very limited release of records from his current hospital. Family is updating on condition, but are not technical historians. ' (Site from Safety).	Whitney West (b) (4)	22 Dec 2020 15:10:42
User opened query 'PV Query:It would be appreciated, if the site provides the rationale of the event term cytokine storm. ' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:19:04
DataPoint Verified.		17 Dec 2020 17:37:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
User entered '16NOV2020- PCT CALLED AND REPORT 02 IN 80S%. DIRECTED TO ER FOR SUSTAINED HYPOXIA 78% ON ROOM AIR. PCT ESCALATED TO BIPAP WITH 02 75% AND TRANSFERRED TO ICU. CHEST X-RAY-BILATERAL PNEUMONIA, CT ANGIO R/O LARGE PE, D-DIMER NEGATIVESTARTED ON ALBUTEROL SULFATE, DELTASONE, CEFTRIAZONE, AZITHROMYCIN, DEXAMETHASONE, ENOXAPARIN, REMDESEVIR STARTED UPON ADMISSION. LAB REVEALS CRT 1.64- ACUTE KIDNEY INJURY- HYDRATION STARTED THEN STOPPED. BEGINS LORAZEPAM FOR ANXIETY SECONDARY TO OXYGEN MASKS. CONVALESCENT PLASMA. LASIX FOR EDEMA. 23NOV BIPAP 100 FIO2. BLOOD AND SPUTUM CULTURES NEGATIVE. ELEVATED DDIMER- KIDNEY/LUNG FUNCTION R/O SCANS. INCREASED ENOXAPARIN. EKG FOR STARTING RUXOLITINIB CLINICAL DRUG INITIATION ON 24NOV2020. CONTINUED DETERIORATION. DEXMEDETOMIDINE INFUSION STARTED 26NOV- STILL SYMPTOMATIC AND FULL BIPAP SUPPORT. STARTED SUPPLEMENTS FOR IMMUNE SUPPORT ON 27NOV, INCREASED STEROIDS. 28NOV EMERGENT INTUBATION AFTER SEVERE COUGHING SPELL C EXTREME RESP DISTRESS. TACHYPNEIC, TACHYCARDIC, AND CYANOTIC APPEARANCE. ID FOLLOWING. INHALED EPOPROSTENOL. OG, ETT, RIGHT RAD ART LINE. MIDLINE INSERTED. EPOPROSTENOL, FENTANYL, PROPOFOL INITIATED. VASOPRESSORS STARTED AND STOPPED. ACUTE KIDNEY INJURY RESOLVED. SPUTUM CULTURES NEGATIVE AGAIN. NEED ESCALATION TO ECMO, TRANSFERRED TO REGIONAL HOSPITAL 01DEC2020. TTE, BRONCH, DOPPLERS TO PREP FOR ECMO PLACEMENT.	Whitney West (b) (4)	14 Dec 2020 20:57:37

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
LASIX CONTINUED. TUBE FEEDINGS WITH Q6 INSULIN. NICARDIPINE STARTED AND STOPPED. VV ECMO PLACEMENT 02DEC2020. PCR ON 02DEC2020 STILL POSITIVE FOR COVID-19. PER FAMILY REPORT, PARTICIPANT RECEIVED TRACHEOSTOMY ON 10DEC2020, STILL RECEIVING TREATMENT, MEDICAL TEAM ESTIMATES MULTIPLE WEEKS BEFORE BEGINNING TO TRY TO WEAN SEDATION ON THE PARTICIPANT. STILL ON ECMO AND VENT.'		

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered 'I'	System	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	14 Dec 2020 20:57:37

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:47:57
Reviewed for Safety.		05 Feb 2021 14:21:49
User entered 'USA-US070-2020-mRNA-1273-P301000019'		05 Feb 2021 14:21:36

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:48:00
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Respiratory tract and thoracic cavity procedural complications, PT: Tracheal haemorrhage, LLT: Tracheal hemorrhage - version MedDRA\23.0.	Coder Import (b) (4)	04 Feb 2021 23:21:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Feb 2021 23:21:33
Data point term sent to Coder	System	04 Feb 2021 23:21:00
User entered 'Tracheal hemorrhage'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:48:02
User entered 'Yes (Y)'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:48:04
User entered 'No (N)'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

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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)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:48:07
User entered 'No (N)'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:48:10
User entered '20 Jan 2021' reason for change: Data Entry Error	Whitney West (b) (4)	15 Feb 2021 17:49:34
User entered '21 Jan 2021'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:48:12
User entered empty.	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:48:15
User entered 'No (N)'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:48:17
User entered '21 Jan 2021' reason for change: Data Entry Error	Whitney West (b) (4)	15 Feb 2021 17:49:34
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	04 Feb 2021 23:21:31
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	04 Feb 2021 23:21:31
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	04 Feb 2021 23:21:31
User entered '22 Jan 2021' reason for change: Data Entry Error	Whitney West (b) (4)	04 Feb 2021 23:21:31
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	04 Feb 2021 23:20:59
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	04 Feb 2021 23:20:59
User entered empty.	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:48:19
User entered empty.	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:48:22
User entered 'Grade 4 (Grade 4)'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:48:24
User entered 'Yes (Y)'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:48:58
User entered '0'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:00
User entered '0'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:02
User entered 'l'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:05
User closed query 'PV Query: Please confirm hospitalization dates of AE #6. Hospitalization date is a day before event onset date. ' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 17:55:28
Query 'PV Query: Please confirm hospitalization dates of AE #6. Hospitalization date is a day before event onset date. ' answered with 'Dates updated. ' (Site from Safety).	Whitney West (b) (4)	15 Feb 2021 17:49:49
User opened query 'PV Query: Please confirm hospitalization dates of AE #6. Hospitalization date is a day before event onset date. ' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 16:41:58
User entered '20 Jan 2021'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:10
User entered '28 Jan 2021' reason for change: Data Entry Error	Whitney West (b) (4)	15 Feb 2021 17:49:34
User entered '20 Jan 2021'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:13
User entered 'No (N)'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:18
User entered empty.	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:20
User entered '0'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:21
User entered '0'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:24
User entered '0'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:27
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:29
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:31
User closed query 'AE #6 PV Query: As the event occurred after the second dose of the study drug, please update the action taken with study drug from none to not applicable.' (Site from Safety).		16 Feb 2021 17:55:41
Query 'AE #6 PV Query: As the event occurred after the second dose of the study drug, please update the action taken with study drug from none to not applicable.' answered with 'Updated.' (Site from Safety).	Whitney West (b) (4)	15 Feb 2021 17:50:46
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Whitney West (b) (4)	15 Feb 2021 17:49:34
User opened query 'AE #6 PV Query: As the event occurred after the second dose of the study drug, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 16:42:19
User entered 'None (NONE)'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:38
User entered '0'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:40
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:55:27
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'Will add all diagnoses to all meds per query instruction.' (Site from DM).	Whitney West (b) (4)	16 Feb 2021 16:15:38
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:36:47
User entered 'I'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:44
User entered 'l'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

Form: Adverse Events (6)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	04 Feb 2021 23:20:59

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:49
User entered empty.	Whitney West (b) (4)	04 Feb 2021 23:20:59

US3272026

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:49:51
User entered 'Participant was at a long-term rehabilitation facility on 20JAN2021 when he began bleeding heavily from his tracheostomy site. He was flown back to the hospital where imaging and bronchoscopy were negative for fistula or other cause. Anticoagulation was held and hemorrhaging resolved. Participant remained inpatient for tracheostomy decannulation 25JAN2021. They continued his fondaparinux for fifty (50) more days and will follow up with vascular surgery. He was discharged back to the rehabilitation facility 28JAN2021.'	Whitney West (b) (4)	04 Feb 2021 23:20:59

US3272026

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered 'I'	System	04 Feb 2021 23:20:59

US3272026

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered 'I'	System	04 Feb 2021 23:20:59

US3272026

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '0'	System	04 Feb 2021 23:20:59

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:50:25
User coded data point as SOC: Psychiatric disorders, HLGT: Deliria (incl confusion), HLT: Deliria, PT: Delirium, LLT: Delirium - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 21:42:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 21:42:49
Data point term sent to Coder	System	05 Feb 2021 21:41:58
User entered 'Delirium'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:50:29
User entered 'Yes (Y)'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:50:31
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:50:33
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:50:36
User entered '15 Jan 2021'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User entered empty.	System	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '28 Jan 2021'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User entered empty.	System	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:45:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 21:45:57
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	05 Feb 2021 21:45:57
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:41:09
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User entered '0'	System	05 Feb 2021 21:45:57

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06
User entered 'I'	System	05 Feb 2021 21:41:09

US3272026

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:06

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 21:43:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 21:43:49
Data point term sent to Coder	System	05 Feb 2021 21:42:59
User entered 'Constipation'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '20 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Feb 2021 22:39:53
User entered '15 Jan 2021'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User entered empty.	System	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:42:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 21:42:20
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	05 Feb 2021 21:42:20
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:42:10
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '28 Jan 2021'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User entered empty.	System	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	05 Feb 2021 21:42:10

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:56:11
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'See #65' (Site from DM).	Whitney West (b) (4)	16 Feb 2021 16:16:52
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:32:35
User entered 'I'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	05 Feb 2021 21:42:10

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User entered '0'	System	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55
User entered 'I'	System	05 Feb 2021 21:42:10

US3272026

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:55

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Vascular disorders, HLT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis leg - version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 14:06:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 14:06:38
Data point term sent to Coder	System	05 Feb 2021 22:30:46
User entered 'DEEP VEIN THROMBOSIS, Left Common Femoral/Left Iliac' reason for change: Data Entry Error	Whitney West (b) (4)	05 Feb 2021 22:30:09
Data point term sent to Coder	System	05 Feb 2021 21:43:59
User entered 'Deep vein thrombosis, left lower leg'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '01 Jan 2021'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:45:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 21:45:42
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	05 Feb 2021 21:45:42
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:43:44
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'I'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '1' reason for change: New Information	Whitney West (b) (4)	05 Feb 2021 22:05:18
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:45:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 21:45:42
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Whitney West (b) (4)	05 Feb 2021 21:45:42
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:43:44
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:43:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:43:44

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '0'	System	05 Feb 2021 21:45:42

US3272026

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered 'I'	System	05 Feb 2021 21:43:44

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 21:45:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 21:45:49
Data point term sent to Coder	System	05 Feb 2021 21:45:00
User entered 'Gastroesophageal reflux disease'	Whitney West (b) (4)	05 Feb 2021 21:45:00

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:45:00

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '18 Nov 2020'	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User entered empty.	System	05 Feb 2021 21:45:00

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an AE End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:57:47
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an AE End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'New baseline. Participant denied symptoms after returning home. Controlled with meds. ' (Site from DM).	Whitney West (b) (4)	16 Feb 2021 16:18:25
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	16 Feb 2021 16:17:54
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an AE End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:34:21
User entered 'Yes (Y)'	Whitney West (b) (4)	05 Feb 2021 21:45:00

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '10 Feb 2021' reason for change: Data Entry Error	Whitney West (b) (4)	16 Feb 2021 16:17:54
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Feb 2021 21:45:12
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	05 Feb 2021 21:45:12
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Feb 2021 21:45:00
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:45:00

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:45:00

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User entered empty.	System	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:45:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Feb 2021 21:45:19
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	05 Feb 2021 21:45:19
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Feb 2021 21:45:00
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:45:00

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	05 Feb 2021 21:45:00

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	05 Feb 2021 21:45:00

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Whitney West (b) (4)	16 Feb 2021 16:17:54
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Whitney West (b) (4)	05 Feb 2021 21:45:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User entered '0'	System	05 Feb 2021 21:45:19

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37
User entered '1'	System	05 Feb 2021 21:45:00

US3272026

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:37

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 21:50:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 21:50:49
Data point term sent to Coder	System	05 Feb 2021 21:50:05
User entered 'Tachycardia'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '01 Jan 2021'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '0'	System	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered 'I'	System	05 Feb 2021 21:49:27

US3272026

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
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)	05 Feb 2021 22:02:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 22:02:49
Data point term sent to Coder	System	05 Feb 2021 22:02:19
User entered 'Anxiety'	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '19 Nov 2020' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 21:54:32
User entered '18 Nov 2020'	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User entered empty.	System	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	25 Mar 2021 19:49:06
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an AE End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 09:21:05
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 21:54:32
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an AE End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'Participant denies current symptom. New baseline stable with medication.' (Site from DM).	Whitney West (b) (4)	16 Feb 2021 16:21:28
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	16 Feb 2021 16:20:37
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an AE End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:30:36
User entered 'Yes (Y)'	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '11 Feb 2021' reason for change: New Information	Whitney West (b) (4)	25 Mar 2021 19:49:06
User entered empty; reason for change New Information	Whitney West (b) (4)	17 Feb 2021 21:54:32
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Feb 2021 16:21:01
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	16 Feb 2021 16:21:01
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	16 Feb 2021 16:21:01
User entered '10 Feb 2021' reason for change: Data Entry Error	Whitney West (b) (4)	16 Feb 2021 16:21:01
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	16 Feb 2021 16:20:37
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Feb 2021 16:20:37
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:01:22

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User entered empty.	System	05 Feb 2021 22:01:22

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 3/Severe (Grade 3/Severe)'	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:01:22

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:01:22

US3272026

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:01:22

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	05 Feb 2021 22:01:22

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	05 Feb 2021 22:01:22

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	05 Feb 2021 22:01:22

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:01:22

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	05 Feb 2021 22:01:22

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:01:22

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Whitney West (b) (4)	25 Mar 2021 19:49:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 21:54:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Whitney West (b) (4)	16 Feb 2021 16:20:37
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Whitney West (b) (4)	05 Feb 2021 22:01:22

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Folder: Adverse Events

Form: Adverse Events (12)

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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)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:01:22

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:01:22

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User entered '0'	System	05 Feb 2021 22:01:22

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42
User entered '1'	System	05 Feb 2021 22:01:22

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:42

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'USA-US070-2020-mRNA-1273-P301000019'	(b) (4), (b) (6)	18 Feb 2021 14:28:58

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Enterococcal infections, PT: Enterococcal bacteraemia, LLT: Enterococcal bacteremia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 16:16:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 16:16:58
Data point term sent to Coder	System	05 Feb 2021 22:04:23
User entered 'Vancomycin Resistant Enterococcus BACTEREMIA' reason for change: Data Entry Error	Whitney West (b) (4)	05 Feb 2021 22:03:57
Data point term sent to Coder	System	05 Feb 2021 22:03:20
User entered 'VRE bacteremia'	Whitney West (b) (4)	05 Feb 2021 22:03:06

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	05 Feb 2021 22:03:06

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 22:03:06

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Folder: Adverse Events

Form: Adverse Events (13)

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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)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 22:03:06

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '01 Jan 2021'	Whitney West (b) (4)	05 Feb 2021 22:03:06

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 18:20:18
User entered 'Yes (Y)'	Whitney West (b) (4)	05 Feb 2021 22:03:06

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '19 Jan 2021' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 18:20:18
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	05 Feb 2021 22:03:06

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 4 (Grade 4)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 18:20:18
User entered 'Grade 3/Severe (Grade 3/Severe)'	Whitney West (b) (4)	05 Feb 2021 22:03:06

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
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	17 Feb 2021 18:24:18
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	17 Feb 2021 18:20:18
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 18:20:18
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	18 Feb 2021 15:21:50
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 'Dates are there. ' (Site from System).	Whitney West (b) (4)	17 Feb 2021 18:24:43
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	17 Feb 2021 18:24:18
User entered '1' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 18:24:18
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '16 Nov 2020' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 18:24:18
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '28 Jan 2021' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 18:24:18
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	05 Feb 2021 22:03:06

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	05 Feb 2021 22:03:06

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:59:15
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'Will add' (Site from DM).	Whitney West (b) (4)	16 Feb 2021 16:22:34
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:37:37
User entered 'I'	Whitney West (b) (4)	05 Feb 2021 22:03:06

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	05 Feb 2021 22:03:06

US3272026

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 18:20:18
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Whitney West (b) (4)	05 Feb 2021 22:03:06

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:03:06

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Feb 2021 18:23:06
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	17 Feb 2021 18:23:06
User entered 'Participant continued course of treatment. Blood cultures became positive 01JAN2021. Antibiotics changed to Cefepime. F/U blood cultures were negative.' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 18:23:06
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Feb 2021 18:20:18
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:03:06

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	17 Feb 2021 18:20:18
User entered '0'	System	05 Feb 2021 22:03:06

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	05 Feb 2021 22:03:06

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Epistaxis, LLT: Epistaxis - version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 00:38:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 00:38:51
Data point term sent to Coder	System	06 Feb 2021 22:15:51
User entered 'Right-sided epistaxis'	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '02 Dec 2020'	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User entered empty.	System	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '23 Dec 2020' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 21:52:49
User entered '21 Dec 2020'	Whitney West (b) (4)	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User entered empty.	System	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 3/Severe (Grade 3/Severe)'	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 09:29:37
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'Currently updating meds.' (Site from DM).	Whitney West (b) (4)	17 Feb 2021 15:28:25
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:36:21
User entered 'I'	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'PARTICIPANT WAS STARTED ON HEPARIN FOR INITIATION OF ECMO 02DEC2020 RESULTING IN ON-GOING RIGHT-SIDED EPISTAXIS. THESE WERE TREATED WITH OXYMETAZOLINE NASAL SPRAY AND RHINO ROCKETS ON 13DEC20220 AND 21DEC2020. ANTICOAGULATION WAS CHANGED FROM HEPARIN TO ARGATROBAN WITH RESOLUTION OF SYMPTOMS ON 23DEC2020.' reason for change: Data Entry Error	Whitney West (b) (4)	17 Feb 2021 21:52:49
User entered 'Participant was started on heparin for initiation of ECMO 02DEC2020 resulting in on-going right-sided epistaxis. These were treated with oxymetazoline nasal spray and rhino rockets on 13DEC20220 and 21DEC2020. Anticoagulation was changed from heparin to argatroban with resolution of symptoms on 21DEC2020.'	Whitney West (b) (4)	06 Feb 2021 22:15:31

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User entered '0'	System	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09
User entered 'I'	System	06 Feb 2021 22:15:31

US3272026

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:22:09

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'USA-US070-2020-mRNA-1273-P301000019'		18 Feb 2021 14:32:48

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Pneumonia bacterial, LLT: Ventilator associated bacterial pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 12:21:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 12:21:52
User closed query 'Per DM CLR: Please review the dates of AE #s 2 and 15, as both events were noted as ongoing and have overlapping dates. Please reconcile and update so there is no overlap. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:58:16
Query 'Per DM CLR: Please review the dates of AE #s 2 and 15, as both events were noted as ongoing and have overlapping dates. Please reconcile and update so there is no overlap. Otherwise, clarify.' answered with 'Separate. Ventilator-Associated pseudomonas infection. ' (Site from DM).	Whitney West (b) (4)	16 Feb 2021 16:24:42
User opened query 'Per DM CLR: Please review the dates of AE #s 2 and 15, as both events were noted as ongoing and have overlapping dates. Please reconcile and update so there is no overlap. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:35:15
Data point term sent to Coder	System	06 Feb 2021 23:48:03
User entered 'PSEUDOMONAS AERUGINOSA, PNEUMONIA, BILATERAL, Ventilator-Associated Pneumonia' reason for change: Data Entry Error	Whitney West (b) (4)	06 Feb 2021 23:47:05
Data point term sent to Coder	System	06 Feb 2021 22:21:53
User entered 'Pseudomonas Aeruginosa, pneumonia, bilateral'	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '04 Dec 2020' reason for change: New Information	Whitney West (b) (4)	06 Feb 2021 23:47:05
User entered '14 Dec 2020'	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an AE End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:58:34
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an AE End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'Updated.' (Site from DM).	Whitney West (b) (4)	16 Feb 2021 16:25:26
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	16 Feb 2021 16:25:11
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	16 Feb 2021 16:25:06
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an AE End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:35:24
User entered 'Yes (Y)'	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '23 Dec 2020' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 22:31:47
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	16 Feb 2021 16:25:48
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	16 Feb 2021 16:25:48
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	16 Feb 2021 16:25:06
User entered '10 Jan 2021' reason for change: New Information	Whitney West (b) (4)	16 Feb 2021 16:25:06
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 4 (Grade 4)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 22:31:47
User entered 'Grade 3/Severe (Grade 3/Severe)'	Whitney West (b) (4)	06 Feb 2021 22:21:05

US3272026

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
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	17 Feb 2021 22:45:06
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	17 Feb 2021 22:31:47
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 22:31:47
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:21:05

US3272026

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:21:05

US3272026

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '1' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 22:45:06
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:21:05

US3272026

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '1' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 22:45:06
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '16 Nov 2020' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 22:45:06
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '23 Dec 2020' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 22:45:06
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 22:45:06
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '60' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 22:45:06
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:21:05

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	06 Feb 2021 22:21:05

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	06 Feb 2021 22:21:05

US3272026

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	06 Feb 2021 22:21:05

US3272026

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:21:05

US3272026

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:58:46
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'Will add this diagnosis to meds.' (Site from DM).	Whitney West (b) (4)	16 Feb 2021 16:26:06
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 07:35:52
User entered 'I'	Whitney West (b) (4)	06 Feb 2021 22:21:05

US3272026

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	06 Feb 2021 22:21:05

US3272026

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Whitney West (b) (4)	16 Feb 2021 16:25:48
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Whitney West (b) (4)	06 Feb 2021 22:21:05

US3272026

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:21:05

US3272026

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Feb 2021 22:45:06
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	17 Feb 2021 22:45:06
User entered '14Dec2020 bronchoscopy culture revealed pseudomonas aeruginosa pneumonia, bilaterally. Participant was ventilated. Started on Levofloxacin 750mg daily 24DEC2020 to 05JAN2021. Still cultured for pseudomonas, changed to Ceftazidime 2g Q8 from 05JAN2021 to 15JAN2021.' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 22:45:06
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Feb 2021 22:31:47
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:21:05

US3272026

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	17 Feb 2021 22:31:47
User entered '0'	System	06 Feb 2021 22:21:05

US3272026

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered 'I'	System	06 Feb 2021 22:21:05

US3272026

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered 'I'	System	17 Feb 2021 22:45:06

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 16:52:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 16:52:02
Data point term sent to Coder	System	17 Feb 2021 16:51:18
User entered 'Insomnia'	Whitney West (b) (4)	17 Feb 2021 16:51:07

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	17 Feb 2021 16:51:07

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 16:51:07

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 16:51:07

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '15 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 16:51:07

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	17 Feb 2021 16:51:07

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 16:52:06
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty; reason for change New Information	Whitney West (b) (4)	17 Feb 2021 16:52:06
User entered '28 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	17 Feb 2021 16:51:07

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 16:51:07

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 16:51:07

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 16:51:07

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 16:51:07

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 16:51:07

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 16:51:07

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	17 Feb 2021 16:51:07

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 16:51:07

US3272026

Folder: Adverse Events

Form: Adverse Events (17)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Whitney West (b) (4)	17 Feb 2021 16:52:06
Data Entry Error	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	17 Feb 2021 16:51:07
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:51:07

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Folder: Adverse Events

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '0'	System	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered 'I'	System	17 Feb 2021 16:51:07

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 20:02:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 20:02:02
Data point term sent to Coder	System	17 Feb 2021 20:00:42
User entered 'Hypertension'	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '02 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	17 Feb 2021 20:00:32

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Feb 2021 20:00:46
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	17 Feb 2021 20:00:46
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	17 Feb 2021 20:00:32
User entered empty.	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 3/Severe (Grade 3/Severe)'	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 20:00:32

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 20:00:32

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 20:00:32

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 20:00:32

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	17 Feb 2021 20:00:32

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	17 Feb 2021 20:00:32

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	17 Feb 2021 20:00:32

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 20:00:32

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	17 Feb 2021 20:00:32

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 20:00:32

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Whitney West (b) (4)	17 Feb 2021 20:00:46
Data Entry Error	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	17 Feb 2021 20:00:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 20:00:32

US3272026

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 20:00:32

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '0'	System	17 Feb 2021 20:00:32

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	17 Feb 2021 20:00:32

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'USA-US070-2020-mRNA-1273-P301000019'		18 Feb 2021 14:29:41

US3272026

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
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)	17 Feb 2021 20:04:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 20:04:02
Data point term sent to Coder	System	17 Feb 2021 20:03:47
User entered 'Thrombocytopenia'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	17 Feb 2021 20:03:01

US3272026

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 20:03:01

US3272026

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 20:03:01

US3272026

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '09 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 20:03:01

US3272026

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 20:03:01

US3272026

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	17 Feb 2021 20:03:01

US3272026

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '01 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	17 Feb 2021 20:03:01

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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)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 4 (Grade 4)'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '16 Nov 2020'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '01 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '60'	Whitney West (b) (4)	17 Feb 2021 20:03:01

US3272026

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 20:03:01

US3272026

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 20:03:01

US3272026

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Feb 2021 21:31:51
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	17 Feb 2021 21:31:51
User entered 'Platelets 142k to 69k 09DEC2020. On Heparin drip secondary to ECMO. Heme/Onc referral. HIT antibodies positive with moderate rise to 1.34. Serotonin release assay study ruled out true HIT, consider reaction to be post-pump syndrome induced thrombocytopenia. Heparin changed to argatroban to Fondaparinux. Heme/Onc considered thrombocytopenia resolved 01JAN2021, signed off.' reason for change: Data Entry Error	Whitney West (b) (4)	17 Feb 2021 21:31:51
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Feb 2021 20:03:01
User entered empty.	Whitney West (b) (4)	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (19)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	17 Feb 2021 20:03:01

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'USA-US070-2020-mRNA-1273-P301000019'		18 Feb 2021 14:32:12

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Pulmonary oedemas, PT: Acute respiratory distress syndrome, LLT: Adult respiratory distress syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 22:09:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 22:09:12
Data point term sent to Coder	System	17 Feb 2021 22:07:57
User entered 'Adult respiratory distress syndrome'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 22:07:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 22:07:50
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 22:07:50
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 22:07:38
User entered empty.	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '16 Nov 2020'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '20 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 4 (Grade 4)'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 22:07:38

US3272026

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'I'	Whitney West (b) (4)	17 Feb 2021 22:07:38

US3272026

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'I'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '16 Nov 2020'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '20 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Form: Adverse Events (20)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '60'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	17 Feb 2021 22:07:38

US3272026

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	17 Feb 2021 22:07:38

US3272026

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	17 Feb 2021 22:07:38

US3272026

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	17 Feb 2021 22:07:38

US3272026

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
Query 'Per CDM: 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' canceled (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:47:18
User opened query 'Per CDM: 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)	22 Mar 2021 14:39:50
User entered 'I'	Whitney West (b) (4)	17 Feb 2021 22:07:38

US3272026

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'I'	Whitney West (b) (4)	17 Feb 2021 22:07:38

US3272026

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Whitney West (b) (4)	17 Feb 2021 22:07:38

US3272026

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Increased O2 needs: Baseline: 1L/NC HS: 2L/NC Activity: 3L/NC'	Whitney West (b) (4)	17 Feb 2021 22:07:38

US3272026

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Feb 2021 22:08:34
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	17 Feb 2021 22:08:34

US3272026

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ADMITTED FOR ARDS D/T COVID-19 VIRUS. DIAGNOSED WITH COVID PNEUMONIA IN MID-NOVEMBER 2020 AND SUBSEQUENTLY DEVELOPED RESPIRATORY FAILURE D/T ASSOCIATED ARDS AND REQUIRED EMERGENT INTUBATION AT THE END OF THE MONTH DUE TO SEVERE HYPOXIA. DESPITE MAXIMAL VENT SETTINGS, THE PATIENT COULD NOT MAINTAIN ADEQUATE OXYGEN SATURATION AND WAS SENT TO A REGIONAL HOSPITAL AT THE BEGINNING OF DECEMBER FOR EVALUATION FOR VV ECMO. PARTICIPANT WAS CANNULATED AND EVENTUALLY REQUIRED TRACHEOSTOMY D/T PROLONGED VENTILATION REQUIREMENTS. ECMO WAS DECANNULATED 01JAN2021. HOSPITAL COURSE WAS COMPLICATED BY VRE BACTEREMIA, TRACH SITE BLEEDING, EPISTAXIS AND THROMBOCYTOPENIA WITH BOTH HEME/ONC AND ID ON BOARD. PARTICIPANT SEROTONIN RELEASE ASSAY IS NEGATIVE MAKING HIT LESS LIKELY. PARTICIPANT COMPLETED ANTIBIOTICS AND WAS STARTED ON PREDNISONE WITH CONCERN CAP. ON PREDNISONE TAPER WITH BACTRIM ON BOARD. DISMISSED TO LOCAL REHAB FACILITY WHERE HE HAD HEMORRHAGING FROM HIS TRACHEA AND WAS TRANSFERRED BACK FOR EVALUATION. HEMORRHAGE RESOLVED WITHOUT INTERVENTION, TRACHEOSTOMY DECANNULATION 25JAN2021. TUBE FEEDINGS STOPPED AS PO RESUMED. DISCHARGED HOME 12FEB2021. INCREASED O2 NEEDS, 1L/NC BASELINE, 2L/NC HS, 3L/NC WITH ACTIVITY.' reason for change: New Information	Whitney West (b) (4) (b) (4)	17 Feb 2021 22:08:34
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Feb 2021 22:07:38

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Whitney West (b) (4) (b) (4)	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered 'I'	System	17 Feb 2021 22:07:38

US3272026

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered 'I'	System	17 Feb 2021 22:07:38

US3272026

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	17 Feb 2021 22:07:38

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Gastrointestinal disorders, HLGT: Oral soft tissue conditions, HLT: Stomatitis and ulceration, PT: Mouth ulceration, LLT: Oral ulceration - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 14:05:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 14:05:51
Data point term sent to Coder	System	18 Feb 2021 14:05:25
User entered 'Oral ulcerations'	Whitney West (b) (4)	18 Feb 2021 14:04:44

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:04:44

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '02 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 14:04:44

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:04:44

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User entered empty.	System	18 Feb 2021 14:04:44

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:04:44

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '10 Feb 2021'	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:04:44

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User entered empty.	System	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 14:05:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 14:05:01
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	18 Feb 2021 14:05:01
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 14:04:44
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:04:44

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	18 Feb 2021 14:04:44

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:04:44

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	18 Feb 2021 14:04:44

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	18 Feb 2021 14:04:44

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	18 Feb 2021 14:04:44

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	18 Feb 2021 14:04:44

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	18 Feb 2021 14:04:44

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Developed oral ulcerations secondary to prolonged intubation.'	Whitney West (b) (4)	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User entered '0'	System	18 Feb 2021 14:05:01

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45
User entered '1'	System	18 Feb 2021 14:04:44

US3272026

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:45

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 14:58:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 14:58:42
Data point term sent to Coder	System	23 Mar 2021 19:10:12
Coding entries removed.	Whitney West (b) (4)	23 Mar 2021 19:10:05
User entered 'LEFT POSTERIOR SHOULDER, NON-PRURITIC, non-urticarial, CIRCULAR RASH' reason for change: Data Entry Error	Whitney West (b) (4)	23 Mar 2021 19:10:05
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Rash - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 12:59:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Mar 2021 12:59:37
Data point term sent to Coder	System	27 Feb 2021 20:15:47
User entered 'LEFT POSTERIOR SHOULDER, non-pruritic, circular rash' reason for change: Data Entry Error	Whitney West (b) (4)	27 Feb 2021 20:15:24
Data point term sent to Coder	System	24 Feb 2021 14:17:41
User entered 'Left posterior shoulder rash'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Feb 2021 20:15:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Feb 2021 20:15:24
User entered '17 Jan 2021' reason for change: Per Query Resolution	Whitney West (b) (4)	27 Feb 2021 20:15:24
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 14:17:22
User entered empty.	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User entered empty.	System	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	27 Feb 2021 20:15:35
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	27 Feb 2021 20:15:35
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	27 Feb 2021 20:15:24
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	27 Feb 2021 20:15:24
User entered 'No (N)'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	27 Feb 2021 20:15:24
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	27 Feb 2021 20:15:24
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	27 Feb 2021 20:15:24
User entered '24 Jan 2021' reason for change: New Information	Whitney West (b) (4)	27 Feb 2021 20:15:24
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Feb 2021 14:17:22
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	24 Feb 2021 14:17:22
User entered empty.	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User entered empty.	System	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: New Information	Whitney West (b) (4)	27 Feb 2021 20:15:24
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Feb 2021 20:15:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Feb 2021 20:15:24
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	27 Feb 2021 20:15:24
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 14:17:22
User entered empty.	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User entered '0'	System	27 Feb 2021 20:15:24

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Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39
User entered '1'	System	24 Feb 2021 14:17:22

US3272026

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:39

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia steroid-induced - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 06:46:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 06:46:08
Data point term sent to Coder	System	27 Feb 2021 14:27:37
User entered 'Steroid-induced hyperglycemia'	Whitney West (b) (4)	27 Feb 2021 14:27:31

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	27 Feb 2021 14:27:31

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '28 Nov 2020' reason for change: Data Entry Error	Whitney West (b) (4)	27 Feb 2021 16:12:17
User entered '01 Dec 2020'	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User entered empty.	System	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '28 Jan 2021'	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User entered empty.	System	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Feb 2021 14:28:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Feb 2021 14:28:43
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	27 Feb 2021 14:28:43
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Feb 2021 14:27:31
User entered empty.	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	27 Feb 2021 14:27:31

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	27 Feb 2021 14:27:31

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	23 Mar 2021 20:57:52
reason for change: Data Entry Error	(b) (4)	
User entered 'Dose Delayed (DOSE DELAYED)'	Whitney West (b) (4)	27 Feb 2021 14:27:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	27 Feb 2021 14:27:31

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Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User entered '0'	System	27 Feb 2021 14:28:43

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48
User entered '1'	System	27 Feb 2021 14:27:31

US3272026

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:48

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 11:35:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 11:35:36
User closed query 'Per CDM: Please update the event 'PAIN' to reflect the location/type of pain. Please reconcile with the CM eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:22:20
Query 'Per CDM: Please update the event 'PAIN' to reflect the location/type of pain. Please reconcile with the CM eCRF as appropriate.' answered with 'Generalized, non-specific.' (Site from DM).	Whitney West (b) (4)	23 Mar 2021 16:44:17
Data point term sent to Coder	System	23 Mar 2021 16:44:13
Coding entries removed.	Whitney West (b) (4)	23 Mar 2021 16:43:59
User entered 'PAIN, generalized' reason for change: Data Entry Error	Whitney West (b) (4)	23 Mar 2021 16:43:59
User opened query 'Per CDM: Please update the event 'PAIN' to reflect the location/type of pain. Please reconcile with the CM eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 12:58:27
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: Pain - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 21:52:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Mar 2021 21:52:02
Data point term sent to Coder	System	22 Mar 2021 21:50:45
User entered 'Pain'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	22 Mar 2021 21:50:43
User entered '20 Nov 2020' reason for change: Data Entry Error	Whitney West (b) (4)	22 Mar 2021 21:50:43
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	22 Mar 2021 21:50:34
User entered '20 Nov 2029'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User entered empty.	System	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	25 Mar 2021 19:43:50
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	25 Mar 2021 19:43:50
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	25 Mar 2021 19:43:44
User entered 'Yes (Y)'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '11 Feb 2021' reason for change: New Information	Whitney West (b) (4)	25 Mar 2021 19:43:44
User entered empty.	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User entered empty.	System	22 Mar 2021 21:50:34

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 3/Severe (Grade 3/Severe)'	Whitney West (b) (4)	22 Mar 2021 21:50:34

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Whitney West (b) (4)	25 Mar 2021 19:43:44
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User entered '0'	System	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52
User entered 'I'	System	22 Mar 2021 21:50:34

US3272026

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:52

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 22:00:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 22:00:50
Data point term sent to Coder	System	23 Mar 2021 22:00:10
User entered 'Hypokalemia'	Whitney West (b) (4)	23 Mar 2021 21:59:34

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	23 Mar 2021 21:59:34

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '20 Jan 2021'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 21:59:34

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User entered empty.	System	23 Mar 2021 21:59:34

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	25 Mar 2021 19:41:48
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Mar 2021 21:59:34

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '16 Feb 2021' reason for change: New Information	Whitney West (b) (4)	25 Mar 2021 19:41:48
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Mar 2021 19:07:37
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	24 Mar 2021 19:07:37
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Mar 2021 21:59:34
User entered empty.	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User entered empty.	System	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Mar 2021 21:59:34

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Mar 2021 21:59:34

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Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'None (NONE)'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
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).	(b) (4), (b) (6)	07 Apr 2021 11:39:43
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 'ConMed updated. ' (Site from DM).	Whitney West (b) (4)	06 Apr 2021 15:32:58
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)	03 Apr 2021 10:22:53
User entered 'I'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Whitney West (b) (4)	25 Mar 2021 19:41:48
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Whitney West (b) (4)	24 Mar 2021 19:07:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User entered '0'	System	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45
User entered 'I'	System	23 Mar 2021 21:59:34

US3272026

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:21:45

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 22:02:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 22:02:41
Data point term sent to Coder	System	23 Mar 2021 22:02:17
User entered 'Edema, bilateral lower extremities'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '03 Feb 2021'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User entered empty.	System	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '08 Feb 2021'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User entered empty.	System	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
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).	(b) (4), (b) (6)	07 Apr 2021 11:40:21
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 'Medication added. ' (Site from DM).	Whitney West (b) (4)	06 Apr 2021 16:39:57
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)	03 Apr 2021 10:23:50
User entered 'I'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User entered '0'	System	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57
User entered 'I'	System	23 Mar 2021 22:01:34

US3272026

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:19:57

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

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Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Paraesthesia, LLT: Paresthesia lower limb - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 13:55:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 13:55:15
Data point term sent to Coder	System	24 Mar 2021 22:36:13
User entered 'Left lower leg paresthesia'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '10 Jan 2021'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
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).	(b) (4), (b) (6)	07 Apr 2021 11:40:42
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 'It is ongoing. ' (Site from DM).	Whitney West (b) (4)	06 Apr 2021 16:41:52
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)	03 Apr 2021 10:24:55
User entered 'Yes (Y)'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 3/Severe (Grade 3/Severe)'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '0'	System	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered 'I'	System	24 Mar 2021 22:35:54

US3272026

Folder: Adverse Events

Form: Adverse Events (28)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Essential tremor, LLT: Essential tremor - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 19:42:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 19:42:30
Data point term sent to Coder	System	25 Mar 2021 19:41:42
User entered 'Essential tremor'	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '28 Jan 2021'	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User entered empty.	System	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	25 Mar 2021 19:41:03

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '15 Mar 2021'	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User entered empty.	System	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	Whitney West (b) (4)	25 Mar 2021 19:41:03

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 19:41:03

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 19:41:03

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 19:41:03

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 19:41:03

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 19:41:03

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Folder: Adverse Events

Form: Adverse Events (29)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 19:41:03

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	25 Mar 2021 19:41:03

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	25 Mar 2021 19:41:03

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 19:41:03

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Folder: Adverse Events

Form: Adverse Events (29)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	25 Mar 2021 19:41:03

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 19:41:03

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 19:41:03

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User entered '0'	System	25 Mar 2021 19:41:03

US3272026

Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14
User entered '1'	System	25 Mar 2021 19:41:03

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Folder: Adverse Events

Form: Adverse Events (29)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:20:14

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Folder: Adverse Events

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

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Folder: Adverse Events

Form: Adverse Events (30)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Paraesthesia, LLT: Paraesthesia - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 14:43:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 14:43:41
Data point term sent to Coder	System	25 Mar 2021 20:15:43
User entered 'Paresthesia of skin, right hand, third, fourth, fifth finger'	Whitney West (b) (4)	25 Mar 2021 20:15:01

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 20:15:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 20:15:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Whitney West (b) (4)	25 Mar 2021 20:15:12
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 20:15:01
User entered empty.	Whitney West (b) (4)	25 Mar 2021 20:15:01

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 20:15:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 20:15:12
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	25 Mar 2021 20:15:12
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 20:15:01
User entered empty.	Whitney West (b) (4)	25 Mar 2021 20:15:01

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 20:15:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Mar 2021 20:15:12
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	25 Mar 2021 20:15:12
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Mar 2021 20:15:01
User entered empty.	Whitney West (b) (4)	25 Mar 2021 20:15:01

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Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '10 Jan 2021'	Whitney West (b) (4)	25 Mar 2021 20:15:01

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Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 20:15:01

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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)	02 May 2021 13:50:11
User entered empty.	System	25 Mar 2021 20:15:01

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
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).	(b) (4), (b) (6)	07 Apr 2021 11:40:51
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 'It is ongoing. ' (Site from DM).	Whitney West (b) (4)	06 Apr 2021 16:42:14
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)	03 Apr 2021 10:25:07
User entered 'Yes (Y)'	Whitney West (b) (4)	25 Mar 2021 20:15:01

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 20:15:01

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Folder: Adverse Events

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 20:15:01

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Folder: Adverse Events

Form: Adverse Events (30)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	25 Mar 2021 20:15:01

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Grade 3/Severe (Grade 3/Severe)'	Whitney West (b) (4)	25 Mar 2021 20:15:01

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	25 Mar 2021 20:15:01

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 20:15:01

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 20:15:01

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 20:15:01

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Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 20:15:01

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Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 20:15:01

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 20:15:01

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 20:15:01

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Folder: Adverse Events

Form: Adverse Events (30)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 20:15:01

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Folder: Adverse Events

Form: Adverse Events (30)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 20:15:01

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 20:15:01

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	25 Mar 2021 20:15:01

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	25 Mar 2021 20:15:01

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	25 Mar 2021 20:15:01

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 20:15:01

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	25 Mar 2021 20:15:01

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	25 Mar 2021 20:15:01

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Whitney West (b) (4)	25 Mar 2021 20:15:01

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 20:15:01

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	25 Mar 2021 20:15:01

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '0'	System	25 Mar 2021 20:15:01

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered 'I'	System	25 Mar 2021 20:15:12

US3272026

Folder: Adverse Events

Form: Adverse Events (30)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

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Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Skin injuries and mechanical dermatoses, PT: Decubitus ulcer, LLT: Pressure sore - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 13:39:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 13:39:44
Data point term sent to Coder	System	06 Apr 2021 16:33:52
User entered 'Pressure sores, nose, bilateral cheeks, coccyx'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Yes (Y)'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '01 Dec 2020'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User entered empty.	System	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'No (N)'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '13 Feb 2021'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User entered empty.	System	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 16:33:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Apr 2021 16:33:41
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Whitney West (b) (4)	06 Apr 2021 16:33:41
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 16:33:33
User entered empty.	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 16:33:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Apr 2021 16:33:41
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	06 Apr 2021 16:33:41
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 16:33:33
User entered empty.	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Related (NOT RELATED)'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Not Applicable (NOT APPLICABLE)'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'l'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered '0'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:18:51
User entered empty.	Whitney West (b) (4)	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User entered '0'	System	06 Apr 2021 16:33:41

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20
User entered '1'	System	06 Apr 2021 16:33:33

US3272026

Folder: Adverse Events

Form: Adverse Events (31)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:18:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per CDM: per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 09:42:13
Query 'Per CDM: per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.' answered with 'Data added' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:32:32
User opened query 'Per CDM: per Sponsor review, the subject received a vaccine outside of the study per the Study Discontinuation CRF. Please agree to add this vaccine to the Concomitant Medication and Vaccination CRF.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 10:44:24
DataPoint Verified.	(b) (4), (b) (6)	21 Aug 2020 15:58:57
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:45:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 16:47:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Aug 2020 16:47:08
Data point term sent to Coder	System	01 Aug 2020 16:46:45
User entered 'fexofenadine'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'seasonal allergies'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '30' reason for change: Data Entry Error	Kayla Flege (b) (4)	05 Sep 2020 04:50:50
User entered '1'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

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US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'You have noted a dose unite of "tablet" kindly enter the dose in mg if known.' (Site from CRA).		30 Sep 2020 20:10:19
Query 'You have noted a dose unite of "tablet" kindly enter the dose in mg if known.' answered with 'updated' (Site from CRA).	Kayla Flege (b) (4)	05 Sep 2020 04:51:01
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	05 Sep 2020 04:50:50
User opened query 'You have noted a dose unite of "tablet" kindly enter the dose in mg if known.' (Site from CRA).	(b) (4), (b) (6)	21 Aug 2020 16:03:33
User entered 'tablet (TABLET)'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'as needed (PRN)'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Oral (ORAL)'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		03 Aug 2020 23:40:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'confirm correct' (Site from System).	Ashley Bell (b) (4)	01 Aug 2020 16:46:06
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	01 Aug 2020 16:45:49
User entered 'un UNK 2013'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	01 Aug 2020 16:45:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Dec 2020 22:25:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Dec 2020 22:25:26
Data point term sent to Coder	System	26 Dec 2020 22:24:32
Coding entries removed.	Whitney West (b) (4)	26 Dec 2020 22:23:33
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 04:04:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 04:04:52
Data point term sent to Coder	System	19 Nov 2020 22:12:12
User entered 'Albuterol sulfate'	Whitney West (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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).		29 Dec 2020 11:22:51
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).	Whitney West (b) (4)	26 Dec 2020 22:23:43
DataPoint Un-verified.	Whitney West (b) (4)	26 Dec 2020 22:23:33
User entered 'Covid-19' reason for change: Per Query Resolution	Whitney West (b) (4)	26 Dec 2020 22:23:33
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).	(b) (4), (b) (6)	23 Dec 2020 23:26:42
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Wheezing'	Whitney West (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
DataPoint Un-verified.	Whitney West (b) (4)	08 Dec 2020 21:53:53
User entered '90' reason for change: Data Entry Error	Whitney West (b) (4)	08 Dec 2020 21:53:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '2.5'	Whitney West (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
DataPoint Un-verified.	Whitney West (b) (4)	08 Dec 2020 21:53:53
User entered 'Other (OTHER)' reason for change:	Whitney West (b) (4)	08 Dec 2020 21:53:53
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'mg (mg)'	Whitney West (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
DataPoint Un-verified.	Whitney West (b) (4)	08 Dec 2020 21:53:53
User entered 'mcgs' reason for change: Data Entry Error	Whitney West (b) (4)	08 Dec 2020 21:53:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'as needed (PRN)'	Whitney West (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Whitney West (b) (4) (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)'	Whitney West (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	19 Nov 2020 22:11:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Dec 2020 12:57:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Dec 2020 12:57:25
Data point term sent to Coder	System	26 Dec 2020 22:26:34
Data point term sent to Coder	System	26 Dec 2020 22:25:33
Coding entries removed.	Whitney West (b) (4)	26 Dec 2020 22:25:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Dec 2020 22:45:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Dec 2020 22:45:18
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
Data point term sent to Coder	System	07 Dec 2020 21:32:19
Coding entries removed.	Whitney West (b) (4)	07 Dec 2020 21:31:19
User entered 'Prednisone' reason for change: New Information	Whitney West (b) (4)	07 Dec 2020 21:31:19
User coded data point as ATC: VARIOUS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, PRODUCT: ALL OTHER NON-THERAPEUTIC PRODUCTS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 03:02:05

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

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.	Coder Import (b) (4)	24 Nov 2020 03:02:05
Data point term sent to Coder	System	23 Nov 2020 22:20:35
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	23 Nov 2020 22:20:25
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'updated' (Site from System).	Kayla Flege (b) (4)	23 Nov 2020 22:20:25
DataPoint Un-verified.	Kayla Flege (b) (4)	23 Nov 2020 22:20:21
User entered 'DELTASONE (Calcium Stearate, Corn Starch, Erythrosine Sodium, Lactose, Mineral Oil, Sorbic Acid and Sucrose.)' reason for change: Data Entry Error	Kayla Flege (b) (4)	23 Nov 2020 22:20:21
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4)	23 Nov 2020 11:02:08
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
Data point term sent to Coder	System	19 Nov 2020 22:13:13
Data point term sent to Coder	System	19 Nov 2020 22:12:12
User entered 'Deltasone'	Whitney West (b) (4)	19 Nov 2020 22:12:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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.'	(b) (4), (b) (6)	29 Dec 2020 11:23:50
(Site from DM).		
User entered 'Multifocal Pneumonia' reason for change: Per Query Resolution	Whitney West (b) (4)	26 Dec 2020 22:26:00
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.'	Whitney West (b) (4)	26 Dec 2020 22:25:29
' answered with 'Updated.' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Whitney West (b) (4)	26 Dec 2020 22:25:18
User entered 'Bilateral pneumonia' reason for change: Per Query Resolution	Whitney West (b) (4)	26 Dec 2020 22:25:18
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.'	(b) (4), (b) (6)	23 Dec 2020 23:27:15
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'respiratory failure' reason for change:	Whitney West (b) (4)	19 Nov 2020 22:13:09
Data Entry Error	(b) (4)	
User entered '10'	Whitney West (b) (4)	19 Nov 2020 22:12:06
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:13:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:13:09
User entered '10' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:13:09
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:12:06
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:12:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:13:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:13:09
User entered 'mg (mg)' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:13:09
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:12:06
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:12:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:12:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:13:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:13:09
User entered 'once daily (QD)' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:13:09
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:12:06
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:12:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:12:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:13:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:13:09
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:13:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Nov 2020 22:12:06
User entered empty.	System	19 Nov 2020 22:12:06
	Whitney West (b) (4)	19 Nov 2020 22:12:06
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:12:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	19 Nov 2020 22:13:09
User entered '16 Nov 2020' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:13:09
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	19 Nov 2020 22:12:06
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:12:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4)	19 Nov 2020 22:12:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
DataPoint Un-verified.	Whitney West (b) (4)	09 Dec 2020 15:28:34
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	09 Dec 2020 15:28:34
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:13:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:13:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:13:09
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:12:06
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:12:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	(Time (GMT)
Data hard locked.	(b) (4), (b) (6)		02 May 2021 03:07:49
User signature succeeded.	Adam Brosz (b) (4)		29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)		17 Dec 2020 19:21:12
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System		09 Dec 2020 15:28:34
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System		09 Dec 2020 15:28:21
DataPoint Un-verified.	Whitney West (b) (4)		09 Dec 2020 15:28:21
User entered '16 Nov 2020' reason for change: Data Entry Error	Whitney West (b) (4)		09 Dec 2020 15:28:21
DataPoint Verified.	(b) (4), (b) (6)		20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)		19 Nov 2020 22:12:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:13:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:13:09
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:13:09
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:12:06
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:12:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User entered '1'	System	19 Nov 2020 22:13:09
User entered empty.	System	19 Nov 2020 22:12:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User entered '1'	System	19 Nov 2020 22:13:09
User entered empty.	System	19 Nov 2020 22:12:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:07:49
User entered '804 (804)'	System	19 Nov 2020 22:13:09
User entered empty.	System	19 Nov 2020 22:12:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 05:49:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 05:49:13
Data point term sent to Coder	System	26 Dec 2020 22:26:36
Coding entries removed.	Whitney West (b) (4)	26 Dec 2020 22:26:22
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, ATC: OTHER RESPIRATORY SYSTEM PRODUCTS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 22:24:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 22:24:03
Data point term sent to Coder	System	19 Nov 2020 22:16:17
User entered 'Dexamethasone'	Whitney West (b) (4)	19 Nov 2020 22:15:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:15:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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).		29 Dec 2020 11:24:53
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).	Whitney West (b) (4)	26 Dec 2020 22:26:29
DataPoint Un-verified.	Whitney West (b) (4)	26 Dec 2020 22:26:22
User entered 'Acute Respiratory Failure' reason for change: Per Query Resolution	Whitney West (b) (4)	26 Dec 2020 22:26:22
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).	(b) (4), (b) (6)	23 Dec 2020 23:27:31
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Acute hypoxic respiratory failure'	Whitney West (b) (4)	19 Nov 2020 22:15:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '20' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:23:06
User entered '10'	Whitney West (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'mg (mg)'	Whitney West (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'once daily (QD)' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 22:23:06
User entered 'once (ONCE)'	Whitney West (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:15:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	09 Feb 2021 20:23:48
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	09 Feb 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 22:23:06
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	09 Feb 2021 20:23:48
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	09 Feb 2021 20:23:48
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty; reason for change New Information	Whitney West (b) (4)	19 Nov 2020 22:23:06
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User entered '1'	System	19 Nov 2020 22:23:06
User entered empty.	System	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User entered '1'	System	19 Nov 2020 22:23:06
User entered empty.	System	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:27
User entered '804 (804)'	System	19 Nov 2020 22:23:06
User entered empty.	System	19 Nov 2020 22:15:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 05:57:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 05:57:13
Data point term sent to Coder	System	26 Dec 2020 22:27:36
Coding entries removed.	Whitney West (b) (4)	26 Dec 2020 22:26:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 03:33:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 03:33:59
Data point term sent to Coder	System	19 Nov 2020 22:18:19
User entered 'Piperacillin-Tazobactam'	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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).		29 Dec 2020 11:25:17
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).	Whitney West (b) (4)	26 Dec 2020 22:27:00
DataPoint Un-verified.	Whitney West (b) (4)	26 Dec 2020 22:26:54
User entered 'Multifocal Pneumonia' reason for change: Per Query Resolution	Whitney West (b) (4)	26 Dec 2020 22:26:54
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).	(b) (4), (b) (6)	23 Dec 2020 23:27:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Bilateral pneumonia'	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include all components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 16:37:33
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include all components as applicable (e.g., 500/125).' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:05:55
DataPoint Un-verified.	(b) (4), (b) (6)	08 Feb 2021 15:05:45
User entered '3/375' reason for change: New Information	(b) (4), (b) (6)	08 Feb 2021 15:05:45
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include all components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 07:39:03
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '3.375' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 22:29:50
User entered 'UNK'	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
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), (b) (6)	05 Mar 2021 12:10:07
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 'subject states dose correct' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 14:00:22
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)	02 Mar 2021 16:47:33
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'mg (mg)' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 22:29:50
User entered 'Other (OTHER)'	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	19 Nov 2020 22:29:50
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	19 Nov 2020 22:17:34
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'once (ONCE)'	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:29:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 22:29:50
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	19 Nov 2020 22:29:50
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 22:17:34
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User entered empty.	System	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User entered empty.	System	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:16:32
User entered empty.	System	19 Nov 2020 22:17:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Dec 2020 14:22:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Dec 2020 14:22:27
Data point term sent to Coder	System	26 Dec 2020 22:27:36
Coding entries removed.	Whitney West (b) (4)	26 Dec 2020 22:27:26
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 03:51:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 03:51:54
Data point term sent to Coder	System	19 Nov 2020 22:19:21
User entered 'Azithromycin'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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).		29 Dec 2020 11:25:30
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).	Whitney West (b) (4)	26 Dec 2020 22:27:32
DataPoint Un-verified.	Whitney West (b) (4)	26 Dec 2020 22:27:26
User entered 'Multifocal Pneumonia' reason for change: Per Query Resolution	Whitney West (b) (4)	26 Dec 2020 22:27:26
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 23:26:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Bilateral pneumonia'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '500' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 22:22:14
User entered 'UNK'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'mg (mg)' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 22:22:14
User entered 'Other (OTHER)'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	19 Nov 2020 22:22:14
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	19 Nov 2020 22:19:07
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'once daily (QD)' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 22:22:14
User entered 'once (ONCE)'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	17 Feb 2021 23:22:50
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 23:22:50
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	19 Nov 2020 22:22:14
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	17 Feb 2021 23:22:50
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	17 Feb 2021 23:22:45
DataPoint Un-verified.	Whitney West (b) (4)	17 Feb 2021 23:22:45
User entered '24 Nov 2020' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 23:22:45
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty; reason for change New Information	Whitney West (b) (4)	19 Nov 2020 22:22:14
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User entered '1'	System	19 Nov 2020 22:22:14
User entered empty.	System	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User entered '1'	System	19 Nov 2020 22:22:14
User entered empty.	System	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:33
User entered '804 (804)'	System	19 Nov 2020 22:22:14
User entered empty.	System	19 Nov 2020 22:19:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 05:47:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 05:47:38
Data point term sent to Coder	System	26 Dec 2020 22:28:37
Coding entries removed.	Whitney West (b) (4)	26 Dec 2020 22:27:53
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 03:53:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 03:53:58
Data point term sent to Coder	System	19 Nov 2020 22:21:26
User entered 'Ceftriaxone'	Whitney West (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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).		29 Dec 2020 11:25:41
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).	Whitney West (b) (4)	26 Dec 2020 22:28:00
DataPoint Un-verified.	Whitney West (b) (4)	26 Dec 2020 22:27:53
User entered 'Multifocal Pneumonia' reason for change: Per Query Resolution	Whitney West (b) (4)	26 Dec 2020 22:27:53
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).	(b) (4), (b) (6)	23 Dec 2020 23:27:01
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Bilateral pneumonia'	Whitney West (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '2'	Whitney West (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'g (g)'	Whitney West (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'once daily (QD)'	Whitney West (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:20:49
User entered '17 Nov 2020' reason for change: Data Entry Error	Whitney West (b) (4)	18 Feb 2021 16:20:49
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:10:09
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:10:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)'	Whitney West (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:10:09
User entered '24 Nov 2020' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:10:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User entered '1'	System	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User entered '1'	System	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:39
User entered '804 (804)'	System	19 Nov 2020 22:21:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 03:58:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 03:58:06
Data point term sent to Coder	System	19 Nov 2020 22:25:31
User entered 'Enoxaparin'	Whitney West (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)'	Whitney West (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'DVT Prophylaxis'	Whitney West (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '40'	Whitney West (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'mg (mg)'	Whitney West (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'once daily (QD)'	Whitney West (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Subcutaneous (SUBCUTANEOUS)'	Whitney West (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '17 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
DataPoint Un-verified.	Whitney West (b) (4)	11 Dec 2020 00:52:28
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	11 Dec 2020 00:52:28
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)'	Whitney West (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	11 Dec 2020 00:52:28
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	11 Dec 2020 00:51:12
DataPoint Un-verified.	Whitney West (b) (4)	11 Dec 2020 00:51:12
User entered '01 Dec 2020' reason for change: New Information	Whitney West (b) (4)	11 Dec 2020 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User entered '1'	System	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User entered '1'	System	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:43
User entered '804 (804)'	System	19 Nov 2020 22:24:34

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 22:27:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 22:27:09
Data point term sent to Coder	System	19 Nov 2020 22:26:32
User entered 'Remdesivir'	Whitney West (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Covid 19'	Whitney West (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '100'	Whitney West (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'mg (mg)'	Whitney West (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'once daily (QD)'	Whitney West (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '16 Nov 2020'	Whitney West (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered '0'	Whitney West (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
DataPoint Un-verified.	Whitney West (b) (4)	08 Dec 2020 11:01:29
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	08 Dec 2020 11:01:29
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'Yes (Y)'	Whitney West (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:20:00
User entered '21 Nov 2020' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:20:00
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
DataPoint Un-verified.	Whitney West (b) (4)	08 Dec 2020 11:01:29
User entered '22 Nov 2020' reason for change: New Information	Whitney West (b) (4)	08 Dec 2020 11:01:29
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered empty.	Whitney West (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:50:17
User entered 'No (N)'	Whitney West (b) (4)	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User entered '1'	System	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User entered '1'	System	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:18:49
User entered '804 (804)'	System	19 Nov 2020 22:25:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: IPRATROPIUM/ALBUTEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 22:35:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 22:35:53
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
Data point term sent to Coder	System	07 Dec 2020 20:38:19
User entered 'Ipratropium-albuterol'	Whitney West (b) (4)	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19, Acute respiratory failure with hypoxia, ARDS, acute encephalopathy'	Whitney West (b) (4)	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0.5-2.5/3'	Whitney West (b) (4)	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Other (OTHER)'	Whitney West (b) (4)	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg/mL'	Whitney West (b) (4)	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'as needed (PRN)'	Whitney West (b) (4)	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Whitney West (b) (4) (b) (4)	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	07 Dec 2020 21:30:38
User entered '16 Nov 2020' reason for change: New Information	Whitney West (b) (4)	07 Dec 2020 21:30:38
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	07 Dec 2020 20:37:27
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:53:32
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:08:41
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:08:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 21:30:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 21:30:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Whitney West (b) (4)	07 Dec 2020 21:30:38
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:37:27
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:53:45
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:08:41
User entered '24 Nov 2020' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:08:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 21:30:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 21:30:38
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	07 Dec 2020 21:30:38
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 20:37:27
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User entered empty.	System	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User entered empty.	System	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:12
User entered empty.	System	07 Dec 2020 20:37:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:02:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 10:02:17
Data point term sent to Coder	System	07 Dec 2020 20:47:27
User entered 'furosemide'	Whitney West (b) (4) (b) (4)	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Acute hypoxic respiratory failure secondary to ARDS from COVID 19'	Whitney West (b) (4)	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '60'	Whitney West (b) (4)	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'once daily (QD)'	Whitney West (b) (4)	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '17 Nov 2020'	Whitney West (b) (4)	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	17 Feb 2021 23:20:39
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 23:20:39
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	17 Feb 2021 23:20:39
User entered '18 Nov 2020' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 23:20:39
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User entered '1'	System	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User entered '1'	System	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:16
User entered '804 (804)'	System	07 Dec 2020 20:47:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 10:03:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 10:03:52
Data point term sent to Coder	System	04 Feb 2021 20:53:58
Coding entries removed.	Whitney West (b) (4)	04 Feb 2021 20:53:43
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 10:37:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 10:37:58
Data point term sent to Coder	System	07 Dec 2020 21:30:16
User entered 'Lorazepam'	Whitney West (b) (4)	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication (ANXIETY). 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)	08 Feb 2021 14:49:02
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication (ANXIETY). Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'Hypoxia d/t COVID-19 causing anxiety, but cause is hypoxia d/t COVID-19. ' (Site from DM).	Whitney West (b) (4)	04 Feb 2021 20:54:15
DataPoint Un-verified.	(b) (4)	
User entered 'COVID-19' reason for change: Per Query Resolution	Whitney West (b) (4)	04 Feb 2021 20:53:43
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication (ANXIETY). 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)	04 Feb 2021 20:53:43
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 02:23:40
User entered 'Anxiety secondary to hypoxia due to COVID-19'	(b) (4), (b) (6)	17 Dec 2020 19:21:12
	Whitney West (b) (4)	07 Dec 2020 21:29:16
	(b) (4)	

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '1.0' reason for change: New Information	Whitney West (b) (4)	08 Dec 2020 20:19:40
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 11:02:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 11:02:23
User entered '0.5' reason for change: New Information	Whitney West (b) (4)	08 Dec 2020 11:02:23
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 21:29:16
User entered empty.	Whitney West (b) (4)	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 11:02:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 11:02:23
User entered 'mg (mg)' reason for change: New Information	Whitney West (b) (4)	08 Dec 2020 11:02:23
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 21:29:16
User entered empty.	Whitney West (b) (4)	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 11:02:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 11:02:23
User entered 'as needed (PRN)' reason for change: Data Entry Error	Whitney West (b) (4)	08 Dec 2020 11:02:23
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 21:29:16
User entered empty.	Whitney West (b) (4)	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '17 Nov 2020'	Whitney West (b) (4)	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	17 Feb 2021 23:21:12
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 23:21:12
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	17 Feb 2021 23:21:12
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	17 Feb 2021 23:21:03
DataPoint Un-verified.	Whitney West (b) (4)	17 Feb 2021 23:21:03
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 23:21:03
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User entered empty.	System	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User entered empty.	System	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:21
User entered empty.	System	07 Dec 2020 21:29:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 21:47:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 21:47:15
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 15:21:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 15:21:01
Data point term sent to Coder	System	07 Dec 2020 22:08:00
User entered '0.9 Sodium Chloride'	Whitney West (b) (4)	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Acute Kidney Injury'	Whitney West (b) (4)	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '65'	Whitney West (b) (4)	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mL (mL)'	Whitney West (b) (4)	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	07 Dec 2020 22:08:23
User entered 'other (OTHER)' reason for change: Data Entry Error	Whitney West (b) (4)	07 Dec 2020 22:08:23
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	07 Dec 2020 22:07:57
User entered 'unknown (UNKNOWN)'	Whitney West (b) (4)	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'per hour'	Whitney West (b) (4)	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Whitney West (b) (4)	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '16 Nov 2020'	Whitney West (b) (4)	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '17 Nov 2020'	Whitney West (b) (4)	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User entered empty.	System	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User entered empty.	System	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:25
User entered empty.	System	07 Dec 2020 22:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
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 HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: DEXTROMETHORPHAN-GUAIFENESIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 22:49:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 22:49:54
Data point term sent to Coder	System	07 Dec 2020 22:48:37
User entered 'Dextromethorphan-guaifenesin'	Whitney West (b) (4)	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 14:51:43
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Updated dosages.' (Site from DM).	Whitney West (b) (4)	04 Feb 2021 20:57:09
DataPoint Un-verified.	Whitney West (b) (4)	04 Feb 2021 20:56:31
User entered '400/20' reason for change: Per Query Resolution	Whitney West (b) (4)	04 Feb 2021 20:56:31
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:23:59
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '1'	Whitney West (b) (4)	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	04 Feb 2021 20:56:31
User entered 'mg (mg)' reason for change: Per Query Resolution	Whitney West (b) (4)	04 Feb 2021 20:56:31
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'tablet (TABLET)'	Whitney West (b) (4)	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'twice daily (BID)'	Whitney West (b) (4)	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Oral (ORAL)'	Whitney West (b) (4)	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '22 Nov 2020'	Whitney West (b) (4)	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '01 Dec 2020'	Whitney West (b) (4)	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User entered '2'	System	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User entered '1'	System	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:30
User entered '804 (804)'	System	07 Dec 2020 22:48:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 10:28:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 10:28:11
Data point term sent to Coder	System	07 Dec 2020 22:50:38
User entered 'Fluitcasone Propionate'	Whitney West (b) (4)	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 14:52:57
Query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Updated dosages' (Site from DM).	Whitney West (b) (4)	04 Feb 2021 20:58:35
DataPoint Un-verified.	Whitney West (b) (4)	04 Feb 2021 20:58:26
User entered '50' reason for change: Per Query Resolution	Whitney West (b) (4)	04 Feb 2021 20:58:26
User opened query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:24:20
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '1'	Whitney West (b) (4)	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	04 Feb 2021 20:58:26
User entered 'ug (ug)' reason for change: Per Query Resolution	Whitney West (b) (4)	04 Feb 2021 20:58:26
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Other (OTHER)'	Whitney West (b) (4)	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	04 Feb 2021 20:58:26
User entered empty; reason for change Per Query Resolution	Whitney West (b) (4)	04 Feb 2021 20:58:26
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'spray'	Whitney West (b) (4)	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	04 Feb 2021 20:58:26
User entered 'twice daily (BID)' reason for change:	Whitney West (b) (4)	04 Feb 2021 20:58:26
Per Query Resolution	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'once daily (QD)'	Whitney West (b) (4)	07 Dec 2020 22:50:09
	(b) (4)	

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Nasal (NASAL)'	Whitney West (b) (4)	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '22 Nov 2020'	Whitney West (b) (4)	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '01 Dec 2020'	Whitney West (b) (4)	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User entered '2'	System	04 Feb 2021 20:58:26
User entered '1'	System	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User entered '1'	System	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:31
User entered '804 (804)'	System	07 Dec 2020 22:50:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: PROTEIN KINASE INHIBITORS, PRODUCT: RUXOLITINIB PHOSPHATE, PRODUCTS YNOMY: JAKAFI - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 21:29:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 21:29:51
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
Data point term sent to Coder	System	07 Dec 2020 23:07:43
User entered 'RE- ruxolitinib (JAKAFI) tablet'	Whitney West (b) (4)	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID 19'	Whitney West (b) (4)	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '5'	Whitney West (b) (4)	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'twice daily (BID)'	Whitney West (b) (4)	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Oral (ORAL)'	Whitney West (b) (4)	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '24 Nov 2020'	Whitney West (b) (4)	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:16:37
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:16:37
User entered '01 Dec 2020' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:16:37
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User entered '2'	System	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User entered '1'	System	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:19:58
User entered '804 (804)'	System	07 Dec 2020 23:07:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 10:04:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 10:04:51
Data point term sent to Coder	System	08 Dec 2020 10:57:09
User entered 'Vancomycin'	Whitney West (b) (4) (b) (4)	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Superimposed bacterial infection secondary to COVID-19 illness'	Whitney West (b) (4)	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '1750'	Whitney West (b) (4)	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'twice daily (BID)'	Whitney West (b) (4)	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '28 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	17 Feb 2021 18:25:57
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 18:25:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '29 Dec 2020' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:03:09
DataPoint Un-verified.	Whitney West (b) (4)	17 Feb 2021 18:25:57
User entered '03 Dec 2020' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 18:25:57
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User entered '2'	System	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User entered '1'	System	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:03
User entered '804 (804)'	System	08 Dec 2020 10:56:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
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)	13 Dec 2020 16:14:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Dec 2020 16:14:45
Data point term sent to Coder	System	08 Dec 2020 10:59:10
User entered 'meropenem'	Whitney West (b) (4)	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Superimposed bacterial infection secondary to COVID-19'	Whitney West (b) (4)	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '500'	Whitney West (b) (4)	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'four times daily (QID)'	Whitney West (b) (4)	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '26 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:18:10
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:18:10
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:18:10
User entered '03 Dec 2020' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:18:10
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User entered '4'	System	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User entered '1'	System	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:08
User entered '804 (804)'	System	08 Dec 2020 10:58:50

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: THIAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 11:05:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 11:05:52
Data point term sent to Coder	System	08 Dec 2020 11:05:10
User entered 'Thiamine'	Whitney West (b) (4)	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '100'	Whitney West (b) (4)	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'twice daily (BID)'	Whitney West (b) (4)	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Oral (ORAL)'	Whitney West (b) (4)	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '27 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:18:42
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:18:42
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:18:42
User entered '01 Dec 2020' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:18:42
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User entered '2'	System	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User entered '1'	System	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:13
User entered '804 (804)'	System	08 Dec 2020 11:04:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Dec 2020 11:05:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Dec 2020 11:05:52
Data point term sent to Coder	System	08 Dec 2020 11:05:10
User entered 'Vitamin C'	Whitney West (b) (4)	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '1000'	Whitney West (b) (4)	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'twice daily (BID)'	Whitney West (b) (4)	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Oral (ORAL)'	Whitney West (b) (4)	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '27 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '2'	System	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	08 Dec 2020 11:05:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 08:59:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 08:59:10
Data point term sent to Coder	System	08 Dec 2020 11:06:11
User entered 'Vitamin D'	Whitney West (b) (4)	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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).		08 Feb 2021 15:01:25
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 'Updated. ' (Site from DM).	Whitney West (b) (4)	04 Feb 2021 20:59:46
DataPoint Un-verified.	Whitney West (b) (4)	04 Feb 2021 20:59:39
User entered '400' reason for change: Per Query Resolution	Whitney West (b) (4)	04 Feb 2021 20:59:39
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)	29 Jan 2021 02:26:07
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '1000'	Whitney West (b) (4)	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	04 Feb 2021 20:59:39
User entered 'IU (IU)' reason for change: Data Entry Error	Whitney West (b) (4)	04 Feb 2021 20:59:39
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'twice daily (BID)'	Whitney West (b) (4)	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Oral (ORAL)'	Whitney West (b) (4)	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '27 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '2'	System	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	08 Dec 2020 11:05:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Dec 2020 11:07:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Dec 2020 11:07:55
Data point term sent to Coder	System	08 Dec 2020 11:07:11
User entered 'Zinc Sulfate'	Whitney West (b) (4)	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '220'	Whitney West (b) (4)	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'once daily (QD)'	Whitney West (b) (4)	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Oral (ORAL)'	Whitney West (b) (4)	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '27 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 11:09:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 11:09:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Whitney West (b) (4)	08 Dec 2020 11:09:18
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 11:06:53
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	08 Dec 2020 11:06:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DEXMEDETOMIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 07:14:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 07:14:02
Data point term sent to Coder	System	08 Dec 2020 11:09:12
User entered 'Dexmedetomidine'	Whitney West (b) (4) (b) (4)	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0.3'	Whitney West (b) (4)	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Other (OTHER)'	Whitney West (b) (4)	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per DM CLR: : Please review the unit and frequency recorded as these reflects the rate of infusion rather than the unit for this medication. Please update the dosage as appropriate with the corresponding unit or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:36:26
Query 'Per DM CLR: : Please review the unit and frequency recorded as these reflects the rate of infusion rather than the unit for this medication. Please update the dosage as appropriate with the corresponding unit or provide explanation for alternate unit. ' answered with 'per subject info correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:52:08
User opened query 'Per DM CLR: : Please review the unit and frequency recorded as these reflects the rate of infusion rather than the unit for this medication. Please update the dosage as appropriate with the corresponding unit or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:14:32
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mcg/kg'	Whitney West (b) (4) (b) (4)	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'other (OTHER)'	Whitney West (b) (4)	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Per hour'	Whitney West (b) (4)	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Whitney West (b) (4)	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '26 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	17 Feb 2021 23:18:54
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 23:18:54
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	17 Feb 2021 23:18:54
User entered '13 Jan 2021' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 23:18:54
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User entered empty.	System	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User entered empty.	System	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:29
User entered empty.	System	08 Dec 2020 11:08:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
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) (b) (4)	13 Dec 2020 14:19:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 14:19:44
Data point term sent to Coder	System	08 Dec 2020 11:12:12
User entered 'Morphine Sulfate'	Whitney West (b) (4) (b) (4)	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Covid-19'	Whitney West (b) (4) (b) (4)	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '2'	Whitney West (b) (4)	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'once (ONCE)'	Whitney West (b) (4)	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '28 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '28 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User entered empty.	System	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User entered empty.	System	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:35
User entered empty.	System	08 Dec 2020 11:11:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: CISATRACURIUM BESILATE, PRODUCTSYNONYM: NIMBEX [CISATRACURIUM BESILATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 06:10:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 06:10:49
Data point term sent to Coder	System	08 Dec 2020 18:46:02
User entered 'Cisatracurium (Nimbex) infusion'	Whitney West (b) (4)	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '3'	Whitney West (b) (4)	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Other (OTHER)'	Whitney West (b) (4)	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the unit recorded as this reflects the rate of infusion rather than the unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		22 Mar 2021 13:36:47
Query 'Per DM CLR: Please review the unit recorded as this reflects the rate of infusion rather than the unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:52:35
User opened query 'Per DM CLR: Please review the unit recorded as this reflects the rate of infusion rather than the unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:13:59
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:57:52
User entered 'MCG/KG/MIN' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:57:52
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mcg/kg'	Whitney West (b) (4)	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	18 Feb 2021 15:58:27
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	18 Feb 2021 15:57:52
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:57:52
User entered 'as needed (PRN)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:57:52
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'other (OTHER)'	Whitney West (b) (4)	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:58:27
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	18 Feb 2021 15:58:27
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'minute'	Whitney West (b) (4)	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Whitney West (b) (4)	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '29 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:57:52
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:57:52
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:57:52
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:57:52
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User entered empty.	System	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User entered empty.	System	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:43
User entered empty.	System	08 Dec 2020 18:45:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: EPOPROSTENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 08:14:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 08:14:16
Data point term sent to Coder	System	08 Dec 2020 18:48:04
User entered 'Epoprostenol'	Whitney West (b) (4)	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per DM CLR: Please review the dose and unit recorded as these are not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:37:12
Query 'Per DM CLR: Please review the dose and unit recorded as these are not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:53:04
User opened query 'Per DM CLR: Please review the dose and unit recorded as these are not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:15:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '8'	Whitney West (b) (4)	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mL (mL)'	Whitney West (b) (4)	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'other (OTHER)'	Whitney West (b) (4)	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'hourly'	Whitney West (b) (4)	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:37:22
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:53:37
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:15:49
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Whitney West (b) (4)	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '29 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:59:42
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:59:42
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:59:42
User entered '29 Nov 2020' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:59:42
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User entered empty.	System	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User entered empty.	System	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:49
User entered empty.	System	08 Dec 2020 18:47:59

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
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)	11 Dec 2020 09:27:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 09:27:50
Data point term sent to Coder	System	08 Dec 2020 18:51:05
User entered 'Fentanyl'	Whitney West (b) (4)	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '162'	Whitney West (b) (4)	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Other (OTHER)'	Whitney West (b) (4)	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the unit recorded as this reflects the rate of infusion rather than the unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		22 Mar 2021 13:37:49
Query 'Per DM CLR: Please review the unit recorded as this reflects the rate of infusion rather than the unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:53:53
User opened query 'Per DM CLR: Please review the unit recorded as this reflects the rate of infusion rather than the unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:30:15
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:01:13
User entered 'MCG/hour' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:01:13
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mcg'	Whitney West (b) (4)	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:01:13
User entered 'as needed (PRN)' reason for change:	Whitney West (b) (4)	18 Feb 2021 16:01:13
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'other (OTHER)'	Whitney West (b) (4)	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:01:13
User entered empty; reason for change New Information	Whitney West (b) (4)	18 Feb 2021 16:01:13
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'hour' reason for change: Data Entry Error	Whitney West (b) (4)	08 Dec 2020 19:02:37
User entered 'daily'	Whitney West (b) (4)	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	08 Dec 2020 19:02:37
User entered '29 Nov 2020' reason for change: Data Entry Error	Whitney West (b) (4)	08 Dec 2020 19:02:37
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	08 Dec 2020 18:50:18
User entered empty.	Whitney West (b) (4)	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:01:13
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:01:13
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 19:02:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 19:02:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Whitney West (b) (4)	08 Dec 2020 19:02:37
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 18:50:18
User entered empty.	Whitney West (b) (4)	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:01:13
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:01:13
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 19:02:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 19:02:37
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	08 Dec 2020 19:02:37
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 18:50:18
User entered empty.	Whitney West (b) (4)	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User entered empty.	System	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User entered empty.	System	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:22:53
User entered empty.	System	08 Dec 2020 18:50:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 20:40:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 20:40:18
Data point term sent to Coder	System	08 Dec 2020 20:21:51
User entered 'Acetaminophen'	Whitney West (b) (4)	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '650'	Whitney West (b) (4)	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'as needed (PRN)'	Whitney West (b) (4)	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Oral (ORAL)'	Whitney West (b) (4)	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '01 Dec 2020'	Whitney West (b) (4)	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	08 Dec 2020 20:21:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #28. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:39:54
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #28. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' answered with 'per protocol they are to be listed separately' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:54:43
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #28. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:10:18
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Dec 2020 20:40:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Dec 2020 20:40:19
Data point term sent to Coder	System	08 Dec 2020 20:22:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Acetaminophen'	Whitney West (b) (4) (b) (4)	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '650'	Whitney West (b) (4)	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'as needed (PRN)'	Whitney West (b) (4)	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Rectal (RECTAL)'	Whitney West (b) (4)	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	08 Dec 2020 20:27:55
User entered '16 Nov 2020' reason for change: Data Entry Error	Whitney West (b) (4)	08 Dec 2020 20:27:55
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	08 Dec 2020 20:22:15
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	09 Feb 2021 20:19:34
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	09 Feb 2021 20:19:34
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	09 Feb 2021 20:19:34
User entered '20 Jan 2021' reason for change: Data Entry Error	Whitney West (b) (4)	09 Feb 2021 20:19:34
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	08 Dec 2020 20:27:55
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	08 Dec 2020 20:27:55
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	08 Dec 2020 20:22:15
User entered '01 Dec 2020'	Whitney West (b) (4)	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User entered empty.	System	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User entered empty.	System	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:23:58
User entered empty.	System	08 Dec 2020 20:22:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 00:12:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 00:12:52
Data point term sent to Coder	System	08 Dec 2020 20:23:53
User entered 'Dexamethasone'	Whitney West (b) (4)	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '20'	Whitney West (b) (4)	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'once daily (QD)'	Whitney West (b) (4)	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '16 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	08 Dec 2020 20:23:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
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)	08 Dec 2020 20:50:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Dec 2020 20:50:46
Data point term sent to Coder	System	08 Dec 2020 20:49:40
User entered 'Diprivan'	Whitney West (b) (4)	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '40'	Whitney West (b) (4)	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Other (OTHER)'	Whitney West (b) (4)	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per DM CLR: Please review the unit and frequency recorded as these reflects the rate of infusion rather than the unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:40:15
Query 'Per DM CLR: Please review the unit and frequency recorded as these reflects the rate of infusion rather than the unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:55:01
User opened query 'Per DM CLR: Please review the unit and frequency recorded as these reflects the rate of infusion rather than the unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:14:48
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mcg/kg'	Whitney West (b) (4) (b) (4)	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'other (OTHER)'	Whitney West (b) (4)	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Minute'	Whitney West (b) (4)	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Whitney West (b) (4)	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '28 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:54:30
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:54:30
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:54:30
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:54:30
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User entered empty.	System	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User entered empty.	System	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:03
User entered empty.	System	08 Dec 2020 20:48:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Dec 2020 22:20:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Dec 2020 22:20:19
Data point term sent to Coder	System	21 Dec 2020 20:22:58
User closed query 'For coding purposes, references indicate different formulations for ROBITUSSIN. Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	21 Dec 2020 20:22:22
Query 'For coding purposes, references indicate different formulations for ROBITUSSIN. Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'Updated.' (Site from System).	Whitney West (b) (4)	21 Dec 2020 20:22:22
DataPoint Un-verified.	Whitney West (b) (4)	21 Dec 2020 20:22:11
User entered 'Guaifenisen' reason for change: Per Query Resolution	Whitney West (b) (4)	21 Dec 2020 20:22:11
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User opened query 'For coding purposes, references indicate different formulations for ROBITUSSIN. Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	Coder Import (b) (4)	16 Dec 2020 19:11:56
Data point term sent to Coder	System	08 Dec 2020 20:52:45
User entered 'Robitussin'	Whitney West (b) (4)	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '600'	Whitney West (b) (4)	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'twice daily (BID)'	Whitney West (b) (4)	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Oral (ORAL)'	Whitney West (b) (4)	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '16 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '2'	System	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	08 Dec 2020 20:52:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 23:57:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 23:57:48
Data point term sent to Coder	System	08 Dec 2020 20:53:45
User entered 'Benzonatate'	Whitney West (b) (4)	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '100'	Whitney West (b) (4)	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'as needed (PRN)'	Whitney West (b) (4)	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Oral (ORAL)'	Whitney West (b) (4)	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '16 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:55:10
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:55:10
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:55:10
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:55:10
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 20:53:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 20:53:50
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	08 Dec 2020 20:53:50
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 20:53:41
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User entered empty.	System	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User entered empty.	System	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:20:57
User entered empty.	System	08 Dec 2020 20:53:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: IMMUNE SERA AND IMMUNOGLOBULINS, ATC: IMMUNOGLOBULINS, ATC: SPECIFIC IMMUNOGLOBULINS, PRODUCT: SPECIFIC IMMUNOGLOBULINS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 06:43:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 06:43:48
Data point term sent to Coder	System	08 Dec 2020 20:57:51
User entered 'Convalescent plasma'	Whitney West (b) (4)	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '200'	Whitney West (b) (4)	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mL (mL)'	Whitney West (b) (4)	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'once (ONCE)'	Whitney West (b) (4)	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:19:34
User entered '16 Nov 2020' reason for change: Data Entry Error	Whitney West (b) (4)	18 Feb 2021 16:19:34
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '17 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 16:19:34
User entered '16 Nov 2020' reason for change: Data Entry Error	Whitney West (b) (4)	18 Feb 2021 16:19:34
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '17 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User entered empty.	System	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User entered empty.	System	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:14
User entered empty.	System	08 Dec 2020 20:57:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: PARAFFIN, PRODUCTSYNONYM: PETROLATUM/MINERAL OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 23:57:41
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 23:57:41
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
Data point term sent to Coder	System	08 Dec 2020 21:02:55
User entered 'Petrolatum mineral oil'	Whitney West (b) (4) (b) (4)	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:03:15
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'This is to buffer the nose during oxygen supplementation secondary to COVID-19. It has been recommended that we match the AE directly to the Indication- another medication was queried for the same issue. Please advise.' (Site from DM).	Whitney West (b) (4)	04 Feb 2021 21:01:56
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:26:49
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'l'	Whitney West (b) (4)	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Other (OTHER)'	Whitney West (b) (4)	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
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), (b) (6)	22 Mar 2021 13:41:18
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 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:55:19
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)	02 Mar 2021 16:47:17
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'line/eye'	Whitney West (b) (4) (b) (4)	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:56:06
User entered 'as needed (PRN)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:56:06
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'other (OTHER)' reason for change: Data Entry Error	Whitney West (b) (4)	09 Dec 2020 15:50:56
User entered 'four times daily (QID)'	Whitney West (b) (4)	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:56:06
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	18 Feb 2021 15:56:06
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Q4 hours' reason for change: Data Entry Error	Whitney West (b) (4)	09 Dec 2020 15:50:56
User entered empty.	Whitney West (b) (4)	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Other (OTHER)'	Whitney West (b) (4)	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'external eyes'	Whitney West (b) (4) (b) (4)	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '28 Nov 2020'	Whitney West (b) (4) (b) (4)	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:56:06
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:56:06
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:56:06
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:56:06
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User entered empty.	System	09 Dec 2020 15:50:56
User entered '4'	System	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User entered empty.	System	09 Dec 2020 15:50:56
User entered '1'	System	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:20
User entered empty.	System	09 Dec 2020 15:50:56
User entered '804 (804)'	System	08 Dec 2020 21:01:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: NOREPINEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:44:45
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 18:44:45
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
Data point term sent to Coder	System	08 Dec 2020 21:32:17
User entered 'Norepinephrine'	Whitney West (b) (4) (b) (4)	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0.05'	Whitney West (b) (4)	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Other (OTHER)'	Whitney West (b) (4)	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mcg/kg'	Whitney West (b) (4)	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'other (OTHER)'	Whitney West (b) (4)	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'minute'	Whitney West (b) (4)	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Whitney West (b) (4)	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '29 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '29 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User entered empty.	System	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User entered empty.	System	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:24
User entered empty.	System	08 Dec 2020 21:31:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 14:57:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 14:57:21
Data point term sent to Coder	System	08 Dec 2020 21:36:20
User entered 'Midazolam'	Whitney West (b) (4) (b) (4)	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 14:10:45
User entered '2-4' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 14:10:45
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '4'	Whitney West (b) (4)	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'other (OTHER)'	Whitney West (b) (4)	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Hourly'	Whitney West (b) (4)	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Whitney West (b) (4)	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '29 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 14:10:52
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	18 Feb 2021 14:10:52
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	18 Feb 2021 14:10:52
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	18 Feb 2021 14:10:45
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 14:10:45
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 14:10:45
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User entered empty.	System	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User entered empty.	System	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:34
User entered empty.	System	08 Dec 2020 21:35:42

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 15:52:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 15:52:58
Data point term sent to Coder	System	18 Feb 2021 15:52:05
Coding entries removed.	Whitney West (b) (4)	18 Feb 2021 15:52:02
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 19:08:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 19:08:52
Data point term sent to Coder	System	08 Dec 2020 21:43:26
User entered 'Famotidine'	Whitney West (b) (4)	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	18 Feb 2021 15:52:02
User entered 'Gastroesophageal reflux disease' reason for change: Data Entry Error	Whitney West (b) (4)	18 Feb 2021 15:52:02
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '20'	Whitney West (b) (4)	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mg (mg)'	Whitney West (b) (4)	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'twice daily (BID)'	Whitney West (b) (4)	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '30 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	05 Feb 2021 21:28:31
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	05 Feb 2021 21:28:31
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:50:56
DataPoint Un-verified.	Whitney West (b) (4)	05 Feb 2021 21:28:31
User entered '28 Jan 2021' reason for change: New Information	Whitney West (b) (4)	05 Feb 2021 21:28:31
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User entered '2'	System	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User entered '1'	System	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:39
User entered '804 (804)'	System	08 Dec 2020 21:43:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: CODEINE;PROMETHAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 19:15:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 19:15:06
Data point term sent to Coder	System	08 Dec 2020 21:55:37
User entered 'Promethazine-codeine'	Whitney West (b) (4)	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '6.25-10'	Whitney West (b) (4)	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	08 Dec 2020 22:15:42
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	08 Dec 2020 21:55:12
User entered 'mg (mg)'	Whitney West (b) (4)	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty; reason for change Per Query Resolution	Whitney West (b) (4)	08 Dec 2020 22:15:42
User entered 'per 5mL'	Whitney West (b) (4)	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'as needed (PRN)'	Whitney West (b) (4)	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Oral (ORAL)'	Whitney West (b) (4)	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '16 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	08 Dec 2020 21:55:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '01 Dec 2020'	Whitney West (b) (4)	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User entered empty.	System	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User entered empty.	System	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:21:45
User entered empty.	System	08 Dec 2020 21:55:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT, PRODUCT: CHLORHEXIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 07:50:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 07:50:32
Data point term sent to Coder	System	23 Mar 2021 19:51:22
Coding entries removed.	Whitney West (b) (4)	23 Mar 2021 19:51:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT, PRODUCT: CHLORHEXIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 07:55:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4), (b) (6)	10 Feb 2021 07:55:43
Data point term sent to Coder	System	09 Feb 2021 18:41:18
Coding entries removed.	Whitney West (b) (4)	09 Feb 2021 18:40:18
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT, PRODUCT: CHLORHEXIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 06:04:29

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

[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 'Chlorhexidine'	Coder Import (b) (4) (b) (4) System Whitney West (b) (4) (b) (4)	11 Dec 2020 06:04:29 11 Dec 2020 00:45:01 11 Dec 2020 00:44:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	09 Feb 2021 18:40:18
User entered 'Yes (Y)' reason for change: New Information	Whitney West (b) (4)	09 Feb 2021 18:40:18
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	11 Dec 2020 00:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per CDM: Response noted. If used as prophylaxis, please provide Indication to reflect this. (eg, Prophylaxis for ...) else, clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:21:32
Query 'Per CDM: Response noted. If used as prophylaxis, please provide Indication to reflect this. (eg, Prophylaxis for ...) else, clarify. Thank you' answered with 'Updated per query resolution. ' (Site from DM).	Whitney West (b) (4)	23 Mar 2021 19:51:34
User entered 'PROPHYLAXIS for prevention of oral candidiasis' reason for change: Per Query Resolution	Whitney West (b) (4)	23 Mar 2021 19:51:13
User opened query 'Per CDM: Response noted. If used as prophylaxis, please provide Indication to reflect this. (eg, Prophylaxis for ...) else, clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:43:54
User closed query 'Per DM CLR: Prophylaxis term was noted. However, no condition prevented was recorded. Please update the indication to reflect the underlying medical condition that this medication is being used to prevent additional to the term of Prophylaxis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:43:54
Query 'Per DM CLR: Prophylaxis term was noted. However, no condition prevented was recorded. Please update the indication to reflect the underlying medical condition that this medication is being used to prevent additional to the term of Prophylaxis. Update eCRF as appropriate. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:55:37
User opened query 'Per DM CLR: Prophylaxis term was noted. However, no condition prevented was recorded. Please update the indication to reflect the underlying medical condition that this medication is being used to prevent additional to the term of Prophylaxis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:13:36

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Whitney West (b) (4)	09 Feb 2021 18:40:18
User entered 'Prophylaxis' reason for change: Data Entry Error	Whitney West (b) (4)	09 Feb 2021 18:40:18
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	11 Dec 2020 00:44:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '15'	Whitney West (b) (4)	11 Dec 2020 00:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'mL (mL)'	Whitney West (b) (4)	11 Dec 2020 00:44:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	11 Dec 2020 00:44:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'twice daily (BID)'	Whitney West (b) (4)	11 Dec 2020 00:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	11 Dec 2020 00:44:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Other (OTHER)'	Whitney West (b) (4)	11 Dec 2020 00:44:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query ' Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM). Query '	(b) (4), (b) (6)	22 Mar 2021 13:44:51
Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:55:54
User opened query ' Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:13:44
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Swish and spit'	Whitney West (b) (4) (b) (4)	11 Dec 2020 00:44:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '01 Dec 2020'	Whitney West (b) (4)	11 Dec 2020 00:44:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	11 Dec 2020 00:44:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	05 Feb 2021 21:29:43
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	05 Feb 2021 21:29:43
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	11 Dec 2020 00:44:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	05 Feb 2021 21:29:43
User entered '28 Jan 2021' reason for change: New Information	Whitney West (b) (4)	05 Feb 2021 21:29:43
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	11 Dec 2020 00:44:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	11 Dec 2020 00:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User entered '2'	System	11 Dec 2020 00:44:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User entered '1'	System	11 Dec 2020 00:44:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:24:58
User entered '804 (804)'	System	11 Dec 2020 00:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
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)	22 Dec 2020 11:46:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 11:46:52
Data point term sent to Coder	System	21 Dec 2020 23:27:15
Coding entries removed.	Whitney West (b) (4)	21 Dec 2020 23:26:52
DataPoint Verified.	(b) (4)	17 Dec 2020 19:21:12
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)	14 Dec 2020 00:31:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 00:31:52
Data point term sent to Coder	System	11 Dec 2020 00:51:02
User entered 'Heparin'	Whitney West (b) (4)	11 Dec 2020 00:50:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	21 Dec 2020 23:26:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Whitney West (b) (4)	21 Dec 2020 23:26:52
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
DataPoint Un-verified.	Whitney West (b) (4)	21 Dec 2020 23:26:52
User entered 'DVT prophylaxis secondary to hospitalization secondary to COVID-19' reason for change: Data Entry Error	Whitney West (b) (4)	21 Dec 2020 23:26:52
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'COVID-19'	Whitney West (b) (4)	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '5000'	Whitney West (b) (4)	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Other (OTHER)'	Whitney West (b) (4)	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Units'	Whitney West (b) (4)	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'four times daily (QID)'	Whitney West (b) (4)	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	11 Dec 2020 00:50:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Subcutaneous (SUBCUTANEOUS)'	Whitney West (b) (4)	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '01 Dec 2020'	Whitney West (b) (4)	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered '0'	Whitney West (b) (4)	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'Yes (Y)'	Whitney West (b) (4)	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered empty.	Whitney West (b) (4)	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:21:12
User entered 'No (N)'	Whitney West (b) (4)	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '4'	System	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	11 Dec 2020 00:50:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: NICARDIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 11:53:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 11:53:48
Data point term sent to Coder	System	21 Dec 2020 23:26:15
User entered 'Nicardipine'	Whitney West (b) (4) (b) (4)	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Covid-19'	Whitney West (b) (4)	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).		08 Feb 2021 15:11:46
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'The medical records did not list any dosages to for this medication. A request for further information from the hospital has been forwarded to their legal department. Site is still working to obtain complete records, request is outstanding.' (Site from DM).	Whitney West (b) (4)	04 Feb 2021 21:03:38
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 02:27:50
User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. Please review and update accordingly including Dose unit' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 19:23:02
Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. Please review and update accordingly including Dose unit' answered with 'Updated.' (Site from DM).	Whitney West (b) (4)	26 Dec 2020 22:28:32
User entered 'UNK' reason for change: Per Query Resolution	Whitney West (b) (4)	26 Dec 2020 22:28:25
User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available. Please review and update accordingly including Dose unit' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 14:45:03
User entered '0'	Whitney West (b) (4)	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Other (OTHER)'	Whitney West (b) (4)	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Unknown'	Whitney West (b) (4)	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'other (OTHER)'	Whitney West (b) (4)	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Infusion'	Whitney West (b) (4)	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Whitney West (b) (4)	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '02 Dec 2020'	Whitney West (b) (4)	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '02 Dec 2020'	Whitney West (b) (4)	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User entered empty.	System	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User entered empty.	System	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:03
User entered empty.	System	21 Dec 2020 23:25:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 10:38:52
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 Feb 2021 10:38:52
Data point term sent to Coder	System	04 Feb 2021 23:26:02
User entered 'Metoprolol tartrate'	Whitney West (b) (4) (b) (4)	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Tachycardia'	Whitney West (b) (4)	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '50' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 14:34:18
User entered '25'	Whitney West (b) (4)	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'three times daily (TID)' reason for change: Data Entry Error	Whitney West (b) (4)	06 Feb 2021 22:29:39
User entered 'twice daily (BID)'	Whitney West (b) (4)	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '02 Jan 2021' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 14:34:18
User entered '25 Jan 2021' reason for change: New Information	Whitney West (b) (4)	06 Feb 2021 22:29:39
User entered '28 Jan 2021'	Whitney West (b) (4)	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 14:34:18
User entered 'Yes (Y)'	Whitney West (b) (4)	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20 Jan 2021' reason for change: Data Entry Error	Whitney West (b) (4)	18 Feb 2021 14:34:18
User entered empty.	Whitney West (b) (4)	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User entered '3'	System	06 Feb 2021 22:29:39
User entered '2'	System	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User entered '1'	System	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:43
User entered '804 (804)'	System	04 Feb 2021 23:25:11

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Feb 2021 20:43:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Feb 2021 20:43:50
Data point term sent to Coder	System	04 Feb 2021 23:28:03
User entered 'Omeprazole'	Whitney West (b) (4)	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Gastroesophageal reflux disease without esophagitis'	Whitney West (b) (4)	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20'	Whitney West (b) (4)	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once daily (QD)'	Whitney West (b) (4)	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:12:35
User entered '28 Jan 2021'	Whitney West (b) (4)	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:45:17
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'still ongoing' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:56:30
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:46:05
User entered 'Yes (Y)'	Whitney West (b) (4)	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	04 Feb 2021 23:27:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V, PRODUCTSYNONYM: PNEUMOVAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 21:59:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 21:59:49
Data point term sent to Coder	System	05 Feb 2021 21:59:17
User entered 'Pneumovax'	Whitney West (b) (4) (b) (4)	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Yes (Y)'	Whitney West (b) (4)	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Prophylaxis'	Whitney West (b) (4)	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0.5'	Whitney West (b) (4)	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mL (mL)'	Whitney West (b) (4)	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once (ONCE)'	Whitney West (b) (4)	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intramuscular (INTRAMUSCULAR)'	Whitney West (b) (4)	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '28 Jan 2021'	Whitney West (b) (4)	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '28 Jan 2021'	Whitney West (b) (4)	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User entered empty.	System	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User entered empty.	System	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:46:38
User entered empty.	System	05 Feb 2021 21:58:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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)	08 Feb 2021 09:21:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 09:21:52
Data point term sent to Coder	System	05 Feb 2021 22:00:17
User entered 'Influenza Quad-QIV'	Whitney West (b) (4)	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Yes (Y)'	Whitney West (b) (4)	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Prophylaxis'	Whitney West (b) (4)	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0.5'	Whitney West (b) (4)	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mL (mL)'	Whitney West (b) (4)	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once (ONCE)'	Whitney West (b) (4)	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intramuscular (INTRAMUSCULAR)'	Whitney West (b) (4)	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '28 Jan 2021'	Whitney West (b) (4)	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '28 Jan 2021'	Whitney West (b) (4)	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User entered empty.	System	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User entered empty.	System	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:54
User entered empty.	System	05 Feb 2021 21:59:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 09:12:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 09:12:51
Data point term sent to Coder	System	06 Feb 2021 17:31:47
User entered 'Cefepime'	Whitney West (b) (4)	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Multifocal pneumonia'	Whitney West (b) (4)	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 17:52:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Feb 2021 17:52:26
User entered '1' reason for change: New Information	Whitney West (b) (4)	15 Feb 2021 17:52:26
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Feb 2021 17:31:07
User entered empty.	Whitney West (b) (4)	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 17:52:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Feb 2021 17:52:26
User entered 'g (g)' reason for change: New Information	Whitney West (b) (4)	15 Feb 2021 17:52:26
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Feb 2021 17:31:07
User entered empty.	Whitney West (b) (4)	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'four times daily (QID)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:13:49
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 17:52:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Feb 2021 17:52:26
User entered 'twice daily (BID)' reason for change: Data Entry Error	Whitney West (b) (4)	15 Feb 2021 17:52:26
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Feb 2021 17:31:07
User entered empty.	Whitney West (b) (4)	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '16 Dec 2020'	Whitney West (b) (4)	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Feb 2021 17:52:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Feb 2021 17:52:26
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	15 Feb 2021 17:52:26
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Feb 2021 17:31:07
User entered empty.	Whitney West (b) (4)	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '22 Dec 2020' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:13:49
User entered '02 Jan 2021' reason for change: New Information	Whitney West (b) (4)	15 Feb 2021 17:52:26
User entered empty.	Whitney West (b) (4)	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User entered '4'	System	18 Feb 2021 16:13:49
User entered '2'	System	15 Feb 2021 17:52:26
User entered empty.	System	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User entered '1'	System	15 Feb 2021 17:52:26
User entered empty.	System	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:26:39
User entered '804 (804)'	System	15 Feb 2021 17:52:26
User entered empty.	System	06 Feb 2021 17:31:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Mar 2021 12:50:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Mar 2021 12:50:47
Data point term sent to Coder	System	27 Feb 2021 20:36:59
Coding entries removed.	Whitney West (b) (4)	27 Feb 2021 20:36:49
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 08:48:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 08:48:57
Data point term sent to Coder	System	06 Feb 2021 22:24:53
User entered 'Bacitracin'	Whitney West (b) (4)	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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)	01 Mar 2021 12:21:06
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 information. Thank you!' (Site from DM).	Whitney West (b) (4)	27 Feb 2021 20:37:08
User entered 'LEFT POSTERIOR SHOULDER, non-pruritic, circular rash' reason for change: New Information	(b) (4)	
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).	Whitney West (b) (4)	27 Feb 2021 20:36:49
User entered 'Left posterior shoulder rash'	(b) (4)	
	(b) (4), (b) (6)	21 Feb 2021 09:16:49
	Whitney West (b) (4)	06 Feb 2021 22:24:48
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'l'	Whitney West (b) (4)	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Other (OTHER)'	Whitney West (b) (4)	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'application- 500 unit/gram ointment'	Whitney West (b) (4)	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'three times daily (TID)'	Whitney West (b) (4)	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Topical (TOPICAL)'	Whitney West (b) (4)	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '25 Dec 2020'	Whitney West (b) (4)	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4) (b) (4)	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	17 Feb 2021 23:11:27
User entered 'Yes (Y)'	Whitney West (b) (4)	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:47:32
Query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:57:16
User opened query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 10:12:43
User entered '09 Feb 2021' reason for change: New Information	Whitney West (b) (4)	17 Feb 2021 23:11:27
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User entered '3'	System	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User entered '1'	System	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:39
User entered '804 (804)'	System	06 Feb 2021 22:24:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 14:23:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 14:23:37
Data point term sent to Coder	System	24 Mar 2021 19:13:22
Coding entries removed.	Whitney West (b) (4)	24 Mar 2021 19:12:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 11:48:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 11:48:56
Data point term sent to Coder	System	06 Feb 2021 22:28:54
User entered 'Hydromorphone 50 mg in dextrose 5% 100mL'	Whitney West (b) (4)	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per CDM: Response noted however, please update indication as per the previous query request. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:21:36
Query 'Per CDM: Response noted however, please update indication as per the previous query request. Thank you.' answered with 'Thank you- updated!' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:13:01
User entered 'EXTRACORPOREAL MEMBRANE OXYGENATION secondary to adult respiratory distress syndrome' reason for change: Data Entry Error	Whitney West (b) (4)	24 Mar 2021 19:12:44
User opened query 'Per CDM: Response noted however, please update indication as per the previous query request. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:49:44
User closed query 'Per DM CLR-RQ: Thank you for the response. As there was an ECMO secondary to ARDS and this medication was indicated for this, the suggestion is to provide "ECMO secondary to ARDS" at the medical indication. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:49:44
Query 'Per DM CLR-RQ: Thank you for the response. As there was an ECMO secondary to ARDS and this medication was indicated for this, the suggestion is to provide "ECMO secondary to ARDS" at the medical indication. Thank you.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:57:31
User opened query 'Per DM CLR-RQ: Thank you for the response. As there was an ECMO secondary to ARDS and this medication was indicated for this, the suggestion is to provide "ECMO secondary to ARDS" at the medical indication. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:36:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update CM Indication field to reflect a medical condition/diagnosis as appropriate. Please reconcile with the MH or AE eCRF as necessary.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 12:20:35
Query 'Per DM CLR: Please update CM Indication field to reflect a medical condition/diagnosis as appropriate. Please reconcile with the MH or AE eCRF as necessary.' answered with 'Would this be better stated sedation for ECMO secondary to ARDS? Or would ARDS/Respiratory failure be the primary and only Indication? Thank you for your guidance!' (Site from DM).	Whitney West (b) (4)	27 Feb 2021 20:39:21
User opened query 'Per DM CLR: Please update CM Indication field to reflect a medical condition/diagnosis as appropriate. Please reconcile with the MH or AE eCRF as necessary.' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 09:17:26
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.' canceled (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 09:17:23
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)	21 Feb 2021 09:17:01
User entered 'Extracorporeal membrane oxygenation'	Whitney West (b) (4)	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).		22 Mar 2021 13:48:22
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:57:37
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:37:01
User entered '0-8'	Whitney West (b) (4)	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	06 Feb 2021 22:28:55
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	06 Feb 2021 22:28:08
User entered 'mg (mg)'	Whitney West (b) (4)	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty; reason for change Data Entry Error	Whitney West (b) (4)	06 Feb 2021 22:28:55
User entered 'titrated as needed'	Whitney West (b) (4)	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'other (OTHER)'	Whitney West (b) (4)	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Continuous'	Whitney West (b) (4)	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Whitney West (b) (4)	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20 Dec 2020'	Whitney West (b) (4)	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20 Jan 2021' reason for change: Data Entry Error	Whitney West (b) (4)	17 Feb 2021 23:10:37
User entered '15 Jan 2021'	Whitney West (b) (4)	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User entered empty.	System	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User entered empty.	System	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:25:45
User entered empty.	System	06 Feb 2021 22:28:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 10:39:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 10:39:53
Data point term sent to Coder	System	06 Feb 2021 22:32:55
User entered 'Metronidazole'	Whitney West (b) (4)	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:06
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:11
User entered 'Multifocal pneumonia'	Whitney West (b) (4)	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:16
User entered '500'	Whitney West (b) (4)	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:27
User entered 'mg (mg)'	Whitney West (b) (4)	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:29
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:31
User entered 'three times daily (TID)'	Whitney West (b) (4)	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:33
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:36
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:37
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:41
User entered '25 Dec 2020'	Whitney West (b) (4)	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:43
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:45
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:48
User entered '15 Jan 2021'	Whitney West (b) (4)	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:01:50
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User entered '3'	System	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User entered '1'	System	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:07
User entered '804 (804)'	System	06 Feb 2021 22:32:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:03:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT THROMBIN INHIBITORS, PRODUCT: ARGATROBAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 08:24:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 08:24:53
Data point term sent to Coder	System	06 Feb 2021 22:33:55
User entered 'Argatroban'	Whitney West (b) (4)	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:03:47
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:03:50
User entered 'Extracorporeal membranous oxygenation'	Whitney West (b) (4)	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:03:58
User closed query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).		01 Mar 2021 12:20:09
Query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Titrated by the minute and not available in records. Participant does not know and hospital will not answer questions. Unable to give any further information.' (Site from DM).	Whitney West (b) (4)	27 Feb 2021 20:40:47
User opened query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 09:17:56
User entered '0-10'	Whitney West (b) (4)	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:04:04
User entered 'Other (OTHER)'	Whitney West (b) (4)	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:04:08
User entered 'mcg/kg/min'	Whitney West (b) (4)	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:04:11
User entered 'other (OTHER)'	Whitney West (b) (4)	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:04:13
User entered 'continuous'	Whitney West (b) (4)	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:04:16
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Whitney West (b) (4)	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:04:18
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:04:21
User entered '20 Dec 2020'	Whitney West (b) (4)	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:04:23
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:04:25
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Feb 2021 22:35:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Feb 2021 22:35:03
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	06 Feb 2021 22:35:03
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Feb 2021 22:33:52
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:04:28
User entered '25 Dec 2020'	Whitney West (b) (4)	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:04:30
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User entered empty.	System	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User entered empty.	System	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:11
User entered empty.	System	06 Feb 2021 22:33:52

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:56:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:17:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:17:17
Data point term sent to Coder	System	17 Feb 2021 18:19:44
Coding entries removed.	Whitney West (b) (4) (b) (4)	17 Feb 2021 18:19:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 12:00:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 12:00:45
Data point term sent to Coder	System	06 Feb 2021 22:36:56
User entered 'Trazodone'	Whitney West (b) (4) (b) (4)	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:56:22
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:56:24
User entered 'DELIRIUM, insomnia' reason for change: Data Entry Error	Whitney West (b) (4)	17 Feb 2021 18:19:03
User entered 'Delirium'	Whitney West (b) (4)	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:56:26
User entered '50'	Whitney West (b) (4)	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:56:29
User entered 'mg (mg)'	Whitney West (b) (4)	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:56:31
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:56:32
User entered 'once daily (QD)'	Whitney West (b) (4)	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:56:35
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:56:38
User entered 'Oral (ORAL)'	Whitney West (b) (4)	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:04:37
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:56:42
User entered '08 Dec 2020' reason for change: Data Entry Error	Whitney West (b) (4)	17 Feb 2021 18:19:03
User entered '05 Dec 2020'	Whitney West (b) (4)	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:56:45
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:56:48
User entered 'Yes (Y)'	Whitney West (b) (4)	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:56:50
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:56:53
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	06 Feb 2021 22:36:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:06:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 09:02:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 09:02:44
Data point term sent to Coder	System	06 Feb 2021 22:37:57
User entered 'Fentanyl'	Whitney West (b) (4)	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:06:59
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:07:00
User entered 'Extracorporeal membranous oxygenation'	Whitney West (b) (4)	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:07:03
User entered '50'	Whitney West (b) (4)	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:07:05
User entered 'Other (OTHER)'	Whitney West (b) (4)	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:07:07
User entered 'mcg/hr'	Whitney West (b) (4)	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:07:09
User entered 'other (OTHER)'	Whitney West (b) (4)	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:07:11
User entered 'every 72 hours'	Whitney West (b) (4)	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:07:13
User entered 'Transdermal (TRANSDERMAL)'	Whitney West (b) (4)	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:07:15
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:07:18
User entered '05 Dec 2020'	Whitney West (b) (4)	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:05:23
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:05:20
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:05:15
User entered '28 Dec 2020'	Whitney West (b) (4)	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:05:13
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User entered empty.	System	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User entered empty.	System	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:36
User entered empty.	System	06 Feb 2021 22:37:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:08:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 08:19:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 08:19:53
Data point term sent to Coder	System	18 Feb 2021 16:11:50
Coding entries removed.	Whitney West (b) (4)	18 Feb 2021 16:10:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 13:03:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 13:03:52
Data point term sent to Coder	System	09 Feb 2021 19:03:55
Coding entries removed.	Whitney West (b) (4)	09 Feb 2021 19:02:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 09:21:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Feb 2021 09:21:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	06 Feb 2021 22:38:57
User entered 'Insulin glargine'	Whitney West (b) (4)	06 Feb 2021 22:38:49
	(b) (4)	

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:08:54
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:04
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)	01 Mar 2021 12:19:35
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 'Entered into EDC. Thank you!' (Site from DM).	Whitney West (b) (4)	27 Feb 2021 20:37:52
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)	21 Feb 2021 09:28:01
User entered 'Steroid-induced hyperglycemia' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:10:58
User entered 'TUBE FEEDINGS secondary to adult respiratory distress syndrome' reason for change: New Information	Whitney West (b) (4)	09 Feb 2021 19:02:58
User entered 'Tube feedings'	Whitney West (b) (4)	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:20
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 19:00:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 19:00:50
User entered '10' reason for change: New Information	Whitney West (b) (4)	09 Feb 2021 19:00:50
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Feb 2021 22:38:49
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:23
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 19:00:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 19:00:50
User entered 'Other (OTHER)' reason for change: New Information	Whitney West (b) (4)	09 Feb 2021 19:00:50
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Feb 2021 22:38:49
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:26
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	09 Feb 2021 19:02:58
User entered 'units' reason for change: Data Entry Error	Whitney West (b) (4)	09 Feb 2021 19:02:58
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	09 Feb 2021 19:00:50
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:31
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 19:00:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 19:00:50
User entered 'once daily (QD)' reason for change: Data Entry Error	Whitney West (b) (4)	09 Feb 2021 19:00:50
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Feb 2021 22:38:49
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:33
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:35
User entered 'Subcutaneous (SUBCUTANEOUS)'	Whitney West (b) (4)	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:38
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:41
User entered '01 Jan 2021' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 16:10:58
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	09 Feb 2021 19:00:50
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	09 Feb 2021 19:00:50
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	06 Feb 2021 22:38:49
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:43
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:45
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	09 Feb 2021 19:02:09
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 19:00:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 19:00:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Whitney West (b) (4)	09 Feb 2021 19:00:50
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Feb 2021 22:38:49
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:48
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	09 Feb 2021 19:02:25
User entered '28 Jan 2021' reason for change: Data Entry Error	Whitney West (b) (4)	09 Feb 2021 19:02:25
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	09 Feb 2021 19:02:09
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	09 Feb 2021 19:00:50
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	09 Feb 2021 19:00:50
User entered '28 Dec 2020'	Whitney West (b) (4)	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:50
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User entered '1'	System	09 Feb 2021 19:00:50
User entered empty.	System	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User entered '1'	System	09 Feb 2021 19:00:50
User entered empty.	System	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:40
User entered '804 (804)'	System	09 Feb 2021 19:00:50
User entered empty.	System	06 Feb 2021 22:38:49

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 19:17:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 19:17:39
Data point term sent to Coder	System	24 Mar 2021 19:17:26
Coding entries removed.	Whitney West (b) (4)	24 Mar 2021 19:16:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 13:08:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 13:08:51
Data point term sent to Coder	System	06 Feb 2021 22:39:58
User entered 'Insulin lispro'	Whitney West (b) (4)	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:09:59
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:10:01
User closed query 'Per CDM: Response noted- As per previous query, please provide the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:23:14
Query 'Per CDM: Response noted- As per previous query, please provide the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'Changed to match AE. ' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:16:50
User entered 'Steroid-induced hyperglycemia' reason for change: Data Entry Error	Whitney West (b) (4)	24 Mar 2021 19:16:35
User opened query 'Per CDM: Response noted- As per previous query, please provide the indication to reflect the underlying medical condition that this medication is being used to prevent/treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:55:40
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:55:40

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:58:05
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	02 Mar 2021 16:38:16
' (Site from DM).		
User entered 'Tube Feedings'	Whitney West (b) (4)	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:10:07
User entered '1-7'	Whitney West (b) (4)	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:10:10
User entered 'Other (OTHER)'	Whitney West (b) (4)	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:10:21
DataPoint Un-verified.		13 Apr 2021 15:10:15
DataPoint Verified.		13 Apr 2021 15:10:12
User entered 'units'	Whitney West (b) (4)	06 Feb 2021 22:39:43
	(b) (4)	

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:10:25
User entered 'four times daily (QID)'	Whitney West (b) (4)	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:10:30
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:10:47
User entered 'Subcutaneous (SUBCUTANEOUS)'	Whitney West (b) (4)	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:10:50
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:10:53
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	09 Feb 2021 19:04:07
User entered '01 Jan 2021' reason for change: New Information	Whitney West (b) (4)	09 Feb 2021 19:04:07
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	06 Feb 2021 22:39:43
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:10:56
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:01
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 19:04:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 19:04:07
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	09 Feb 2021 19:04:07
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Feb 2021 22:39:43
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:04
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	09 Feb 2021 19:04:18
User entered '28 Jan 2021' reason for change: Data Entry Error	Whitney West (b) (4)	09 Feb 2021 19:04:18
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	09 Feb 2021 19:04:07
User entered '28 Dec 2020'	Whitney West (b) (4)	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:07
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User entered '4'	System	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User entered '1'	System	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:54:44
User entered '804 (804)'	System	06 Feb 2021 22:39:43

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:13:20
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)	08 Feb 2021 09:21:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 09:21:52
Data point term sent to Coder	System	06 Feb 2021 22:40:58
User entered 'Influenza Quad-QIV'	Whitney West (b) (4)	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:13:23
User entered 'Yes (Y)'	Whitney West (b) (4)	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:13:27
User entered 'Prophylaxis'	Whitney West (b) (4)	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:13:30
User entered '0.5'	Whitney West (b) (4)	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:13:35
User entered 'mL (mL)'	Whitney West (b) (4)	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:13:40
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:13:42
User entered 'once (ONCE)'	Whitney West (b) (4)	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:13:46
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:13:48
User entered 'Intramuscular (INTRAMUSCULAR)'	Whitney West (b) (4)	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:13:52
User entered empty.	Whitney West (b) (4)	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:13:54
User entered '28 Jan 2021'	Whitney West (b) (4)	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:13:58
User entered '0'	Whitney West (b) (4)	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:14:01
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:14:04
User entered '28 Jan 2021'	Whitney West (b) (4)	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:16:45
User entered 'No (N)'	Whitney West (b) (4)	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User entered empty.	System	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User entered empty.	System	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:03
User entered empty.	System	06 Feb 2021 22:40:32

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:31:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 18:45:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 18:45:34
Data point term sent to Coder	System	09 Feb 2021 18:44:21
User entered 'docusate'	Whitney West (b) (4)	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:31:04
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:31:06
User entered 'Constipation'	Whitney West (b) (4)	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:31:54
User entered '50'	Whitney West (b) (4)	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:31:55
User entered 'mg (mg)'	Whitney West (b) (4)	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:31:58
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:32:00
User entered 'once daily (QD)'	Whitney West (b) (4)	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:32:02
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:32:06
User entered 'Oral (ORAL)'	Whitney West (b) (4)	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:32:11
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:32:14
User entered '01 Dec 2020'	Whitney West (b) (4)	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:32:16
User entered '0'	Whitney West (b) (4)	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:32:18
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:56:12
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:58:22
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:15:03
User entered 'Yes (Y)'	Whitney West (b) (4)	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:32:26
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:32:28
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	09 Feb 2021 18:43:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:32:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 18:46:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 18:46:34
Data point term sent to Coder	System	09 Feb 2021 18:45:22
User entered 'escitalopram oxalate'	Whitney West (b) (4)	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:32:59
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:33:01
User entered 'Anxiety'	Whitney West (b) (4)	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:33:04
User entered '5'	Whitney West (b) (4)	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:33:06
User entered 'mg (mg)'	Whitney West (b) (4)	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:33:10
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:33:12
User entered 'once daily (QD)'	Whitney West (b) (4)	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:33:17
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:33:19
User entered 'Oral (ORAL)'	Whitney West (b) (4)	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:33:21
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:33:32
User entered '21 Jan 2021'	Whitney West (b) (4)	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:33:34
User entered '0'	Whitney West (b) (4)	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:33:36
User entered 'Yes (Y)'	Whitney West (b) (4)	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:33:38
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:33:42
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	09 Feb 2021 18:44:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:36:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 19:06:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 19:06:34
Data point term sent to Coder	System	09 Feb 2021 18:49:25
User entered 'Famotidine'	Whitney West (b) (4)	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:36:27
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:36:31
User entered 'Gastroesophageal reflux disease'	Whitney West (b) (4)	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:36:34
User entered '20'	Whitney West (b) (4)	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:36:41
User entered 'mg (mg)'	Whitney West (b) (4)	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:36:43
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:36:48
User entered 'twice daily (BID)'	Whitney West (b) (4)	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:36:50
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:36:53
User entered 'Oral (ORAL)'	Whitney West (b) (4)	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:36:59
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:37:09
User entered '20 Jan 2021'	Whitney West (b) (4)	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:37:11
User entered '0'	Whitney West (b) (4)	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:37:14
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:53:13
User entered 'Yes (Y)'	Whitney West (b) (4)	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:37:16
User entered '20 Jan 2021' reason for change: Data Entry Error	Whitney West (b) (4)	18 Feb 2021 15:53:13
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:37:18
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User entered '2'	System	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User entered '1'	System	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:33
User entered '804 (804)'	System	09 Feb 2021 18:48:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:38:54
User closed query 'Per CDM: Response does not satisfy query. Please provide explanation for addition of new medication as per the previous query.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:23:51
Query 'Per CDM: Response does not satisfy query. Please provide explanation for addition of new medication as per the previous query.' answered with 'The medication was being titrated to full dose. How do you want it written? There was no exacerbation.' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:19:39
User opened query 'Per CDM: Response does not satisfy query. Please provide explanation for addition of new medication as per the previous query.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:58:27
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:58:27
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:58:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:32:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: OTHER ANTITHROMBOTIC AGENTS, PRODUCT: FONDAPARINUX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 22:19:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 22:19:40
Data point term sent to Coder	System	09 Feb 2021 18:52:33
User entered 'Fondaparinux'	Whitney West (b) (4)	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:38:59
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:02
User entered 'Left lower leg deep vein thrombosis'	Whitney West (b) (4)	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:05
User entered '10'	Whitney West (b) (4)	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:19
User entered 'mg (mg)'	Whitney West (b) (4)	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:21
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:26
User entered 'once daily (QD)'	Whitney West (b) (4)	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:31
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:33
User entered 'Subcutaneous (SUBCUTANEOUS)'	Whitney West (b) (4)	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:35
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:39
User entered '08 Jan 2021' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 14:12:24
User entered '21 Jan 2021'	Whitney West (b) (4)	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:41
User entered '0'	Whitney West (b) (4)	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:43
User entered 'Yes (Y)'	Whitney West (b) (4)	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:45
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:47
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	09 Feb 2021 18:51:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: OTHER ANTITHROMBOTIC AGENTS, PRODUCT: FONDAPARINUX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 22:20:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 22:20:37
Data point term sent to Coder	System	09 Feb 2021 18:54:42
User entered 'Fondaparinux'	Whitney West (b) (4)	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:58
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:39:59
User entered 'Left lower leg, deep vein thrombosis'	Whitney West (b) (4)	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:40:02
User entered '2.5'	Whitney West (b) (4)	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:40:04
User entered 'mg (mg)'	Whitney West (b) (4)	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:40:07
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:40:09
User entered 'once daily (QD)'	Whitney West (b) (4)	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:40:11
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:40:14
User entered 'Subcutaneous (SUBCUTANEOUS)'	Whitney West (b) (4)	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:40:16
User entered empty.	Whitney West (b) (4)	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:40:20
User entered '01 Jan 2021' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 14:12:46
User entered '12 Jan 2021'	Whitney West (b) (4)	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:40:23
User entered '0'	Whitney West (b) (4)	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:40:26
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:40:28
User entered '07 Jan 2021' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 14:12:46
User entered '20 Jan 2021'	Whitney West (b) (4)	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:40:32
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User entered '1'	System	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User entered '1'	System	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:38
User entered '804 (804)'	System	09 Feb 2021 18:53:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:42:54
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: MICONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 10:06:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 10:06:36
Data point term sent to Coder	System	24 Mar 2021 19:20:30
Data point term sent to Coder	System	23 Mar 2021 18:14:27
Coding entries removed.	Whitney West (b) (4) (b) (4)	23 Mar 2021 18:13:53
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: MICONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 14:07:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 14:07:47
Data point term sent to Coder	System	09 Feb 2021 19:39:34
User entered 'Miconazole 2%'	Whitney West (b) (4) (b) (4)	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:42:42
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:42:38
User closed query 'Per CDM: Response does not satisfy query. Please review Indication and specify the location of "RASH" and indicate whether this is 'Urticarial' or 'Non-urticarial' rash. Please update and ensure that there is a corresponding AE/MH record to match the indication as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:24:22
Query 'Per CDM: Response does not satisfy query. Please review Indication and specify the location of "RASH" and indicate whether this is 'Urticarial' or 'Non-urticarial' rash. Please update and ensure that there is a corresponding AE/MH record to match the indication as appropriate. Otherwise, clarify. ' answered with 'Updated for query resolution. ' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:20:34
User entered 'LEFT POSTERIOR SHOULDER NON-PRURITIC, non-urticarial, CIRCULAR RASH' reason for change: Per Query Resolution	Whitney West (b) (4)	24 Mar 2021 19:20:19
User entered 'Left posterior shoulder non-pruritic, circular rash' reason for change: Data Entry Error	Whitney West (b) (4)	23 Mar 2021 18:13:53
User opened query 'Per CDM: Response does not satisfy query. Please review Indication and specify the location of "RASH" and indicate whether this is 'Urticarial' or 'Non-urticarial' rash. Please update and ensure that there is a corresponding AE/MH record to match the indication as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:02:58
User closed query 'Per DM CLR: Please review Indication and specify the location of Rash and indicate whether this is Urticarial or Non-urticarial rash. Please update and ensure that there is a corresponding MH record to match the indication. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:02:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review Indication and specify the location of Rash and indicate whether this is Urticarial or Non-urticarial rash. Please update and ensure that there is a corresponding MH record to match the indication. Otherwise, clarify. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:59:07
User opened query 'Per DM CLR: Please review Indication and specify the location of Rash and indicate whether this is Urticarial or Non-urticarial rash. Please update and ensure that there is a corresponding MH record to match the indication. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:45:00
User entered 'Rash'	Whitney West (b) (4)	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:42:35
User entered 'l'	Whitney West (b) (4)	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:42:33
User entered 'Other (OTHER)'	Whitney West (b) (4)	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:42:31
User entered 'application'	Whitney West (b) (4)	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:42:29
User entered 'twice daily (BID)'	Whitney West (b) (4)	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:41:55
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:41:53
User entered 'Topical (TOPICAL)'	Whitney West (b) (4)	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:41:48
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:41:43
User entered '20 Jan 2021'	Whitney West (b) (4)	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:41:42
User entered '0'	Whitney West (b) (4)	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:41:35
User entered 'No (N)' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:11:19
User entered 'Yes (Y)'	Whitney West (b) (4)	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:41:32
User entered '05 Feb 2021' reason for change: Data Entry Error	Whitney West (b) (4)	18 Feb 2021 15:11:19
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:41:27
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User entered '2'	System	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User entered '1'	System	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:55:55
User entered '804 (804)'	System	09 Feb 2021 19:38:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:43:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIDIARRHEAL MICROORGANISMS, ATC: ANTIDIARRHEAL MICROORGANISMS, PRODUCT: LACTOBACILLUS RHAMNOSUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:22:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 11:22:44
Data point term sent to Coder	System	09 Feb 2021 19:41:35
User entered 'lactobacillus rhamnosus'	Whitney West (b) (4)	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:43:51
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:43:55
User entered 'Multifocal pneumonia'	Whitney West (b) (4)	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:00
User entered '10'	Whitney West (b) (4)	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:02
User entered 'Other (OTHER)'	Whitney West (b) (4)	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:05
User entered 'billion cell capsule'	Whitney West (b) (4)	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:09
User entered 'twice daily (BID)'	Whitney West (b) (4)	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:11
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:14
User entered 'Oral (ORAL)'	Whitney West (b) (4)	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:16
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:20
User entered '20 Jan 2021'	Whitney West (b) (4)	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:23
User entered '0'	Whitney West (b) (4)	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:27
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:28:50
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 21:59:39
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:40:10
User entered 'Yes (Y)'	Whitney West (b) (4)	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:29
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:44:34
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '2'	System	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	09 Feb 2021 19:41:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:45:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTSYNONYM: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Feb 2021 19:46:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Feb 2021 19:46:35
Data point term sent to Coder	System	09 Feb 2021 19:45:45
User entered 'polyethylene glycol'	Whitney West (b) (4)	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:46:00
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:46:02
User entered 'Constipation'	Whitney West (b) (4)	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:46:04
User entered '17'	Whitney West (b) (4)	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:46:06
User entered 'g (g)'	Whitney West (b) (4)	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:46:09
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:46:13
User entered 'as needed (PRN)'	Whitney West (b) (4)	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:46:16
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:46:18
User entered 'Oral (ORAL)'	Whitney West (b) (4)	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:46:29
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:46:37
User closed query 'Per CDM: Please verify if this pertains to (#8) CONSTIPATION (start date 15-JAN-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:13:53
Query 'Per CDM: Please verify if this pertains to (#8) CONSTIPATION (start date 15-JAN-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate. ' answered with 'updated AE dates' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 22:39:02
User opened query 'Per CDM: Please verify if this pertains to (#8) CONSTIPATION (start date 15-JAN-2021) in the AE eCRF? If yes, note that the Con Med start date is prior to the start date of the AE? Please review and reconcile Con Med and AE dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 05:22:53
User entered '20 Nov 2020'	Whitney West (b) (4)	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:46:44
User entered '0'	Whitney West (b) (4)	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:46:49
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:29:14
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:00:09
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:47:52
User entered 'Yes (Y)'	Whitney West (b) (4)	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:46:53
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:46:56
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	09 Feb 2021 19:45:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:48:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: TRIMETHOPRIM SULFAMETHOXAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Mar 2021 09:45:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Mar 2021 09:45:04
User closed query 'Per CDM: Response noted however; CM record #66 is duplicate to CM record #45 'TRIMETHOPRIM-SULFAMETHOXAZOLE'? Please review and delete duplicate record or, otherwise state.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:25:32
Query 'Per CDM: Response noted however; CM record #66 is duplicate to CM record #45 'TRIMETHOPRIM-SULFAMETHOXAZOLE'? Please review and delete duplicate record or, otherwise state.' answered with 'Duplicate. 45 Deleted. Thank you!' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 20:07:20
Data point term sent to Coder	System	24 Mar 2021 19:34:04
Coding entries removed.	Whitney West (b) (4)	24 Mar 2021 19:34:00
User opened query 'Per CDM: Response noted however; CM record #66 is duplicate to CM record #45 'TRIMETHOPRIM-SULFAMETHOXAZOLE'? Please review and delete duplicate record or, otherwise state.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:37:00

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #45. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:37:00
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #45. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:00:37
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #45. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 17:00:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: TRIMETHOPRIM SULFAMETHOXAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 11:29:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Feb 2021 11:29:45
Data point term sent to Coder	System	09 Feb 2021 19:48:48
Data point term sent to Coder	System	09 Feb 2021 19:47:48
User entered 'Trimethoprim-Sulfamethoxazole'	Whitney West (b) (4)	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:48:34
User entered 'Yes (Y)'	Whitney West (b) (4)	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:48:36
User closed query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure AE eCRF is updated to reflect this update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:46:27
Query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure AE eCRF is updated to reflect this update. Else, clarify. ' answered with 'Medical records indicate concern for cryptogenic organizing pneumonia and indicated it was given prophylactically. Subject had an unusual course.' (Site from DM).	Whitney West (b) (4) (b) (4)	06 Apr 2021 16:49:46
User opened query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update indication if applicable or please clarify. If a condition is added to the indication please ensure AE eCRF is updated to reflect this update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:38:08
User closed query 'Per CDM: Response noted- please provide the indication to reflect the underlying medical condition that this medication is being used to prevent rather than the drug class or mechanism of action. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:25:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Query 'Per CDM: Response noted- please provide the indication to reflect the underlying medical condition that this medication is being used to prevent rather than the drug class or mechanism of action. Update eCRF as appropriate.' answered with 'Updated. ' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:34:12
User entered 'Pneumonia PROPHYLAXIS secondary to STEROIDS' reason for change: Data Entry Error	Whitney West (b) (4)	24 Mar 2021 19:34:00
User opened query 'Per CDM: Response noted- please provide the indication to reflect the underlying medical condition that this medication is being used to prevent rather than the drug class or mechanism of action. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:31:15
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:31:15
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:00:42
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 17:00:22
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 19:48:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 19:48:04
User entered 'Prophylaxis for steroids' reason for change: Data Entry Error	Whitney West (b) (4)	09 Feb 2021 19:48:04
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 19:47:35

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
User entered empty.	Whitney West (b) (4) (b) (4)	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:48:40
User entered '800-160'	Whitney West (b) (4)	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:48:42
User entered 'mg (mg)'	Whitney West (b) (4)	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:48:44
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:48:46
User entered 'other (OTHER)'	Whitney West (b) (4)	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:48:47
User entered 'Three times/week'	Whitney West (b) (4)	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:48:51
User entered 'Oral (ORAL)'	Whitney West (b) (4)	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:48:52
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:48:56
User entered '01 Jan 2021'	Whitney West (b) (4)	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:48:58
User entered '0'	Whitney West (b) (4)	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:49:03
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:49:07
User entered '06 Feb 2021'	Whitney West (b) (4)	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:49:10
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User entered empty.	System	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User entered empty.	System	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:16
User entered empty.	System	09 Feb 2021 19:47:35

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:49:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 13:52:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 13:52:54
Data point term sent to Coder	System	09 Feb 2021 19:57:04
User entered 'Quetiapine'	Whitney West (b) (4) (b) (4)	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:49:35
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:49:39
User entered 'Delirium'	Whitney West (b) (4)	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:49:42
User entered '75'	Whitney West (b) (4)	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:49:44
User entered 'mg (mg)'	Whitney West (b) (4)	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:49:46
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:49:49
User entered 'four times daily (QID)'	Whitney West (b) (4)	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:49:52
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:49:56
User entered 'Oral (ORAL)'	Whitney West (b) (4)	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:50:00
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:50:02
User entered '12 Dec 2020' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:14:42
User entered '20 Jan 2021'	Whitney West (b) (4)	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:50:05
User entered '0'	Whitney West (b) (4)	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:50:07
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	18 Feb 2021 15:14:42
User entered 'Yes (Y)'	Whitney West (b) (4)	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:50:09
User entered '20 Jan 2021' reason for change: New Information	Whitney West (b) (4)	18 Feb 2021 15:14:42
User entered empty.	Whitney West (b) (4)	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:50:11
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User entered '4'	System	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User entered '1'	System	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:56:21
User entered '804 (804)'	System	09 Feb 2021 19:56:38

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:50:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 12:09:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 12:09:46
Data point term sent to Coder	System	09 Feb 2021 20:09:20
User entered 'Prednisone'	Whitney West (b) (4) (b) (4)	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:50:21
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:50:24
User entered 'Adult respiratory distress syndrome'	Whitney West (b) (4)	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:50:28
User entered '50'	Whitney West (b) (4)	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:56:59
User entered 'mg (mg)'	Whitney West (b) (4)	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:02
User entered empty.	Whitney West (b) (4)	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:08
User entered 'once daily (QD)'	Whitney West (b) (4)	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:09
User entered empty.	Whitney West (b) (4)	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:12
User entered 'Oral (ORAL)'	Whitney West (b) (4)	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:14
User entered empty.	Whitney West (b) (4)	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:17
User entered '10 Jan 2021'	Whitney West (b) (4)	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:19
User entered '0'	Whitney West (b) (4)	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:22
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:24
User entered '16 Jan 2021'	Whitney West (b) (4)	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:26
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User entered '1'	System	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User entered '1'	System	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:04
User entered '804 (804)'	System	09 Feb 2021 20:09:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:33
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Feb 2021 12:09:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Feb 2021 12:09:46
Data point term sent to Coder	System	09 Feb 2021 20:10:21
User entered 'Prednisone'	Whitney West (b) (4)	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:34
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:37
User entered 'Adult respiratory distress syndrome'	Whitney West (b) (4)	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:42
User entered '40'	Whitney West (b) (4)	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:44
User entered 'mg (mg)'	Whitney West (b) (4)	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:46
User entered empty.	Whitney West (b) (4)	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:50
User entered 'once daily (QD)'	Whitney West (b) (4)	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:52
User entered empty.	Whitney West (b) (4)	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:55
User entered 'Oral (ORAL)'	Whitney West (b) (4)	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:57:58
User entered empty.	Whitney West (b) (4)	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:02
User entered '17 Jan 2021'	Whitney West (b) (4)	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:04
User entered '0'	Whitney West (b) (4)	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:06
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:10
User entered '23 Jan 2021'	Whitney West (b) (4)	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:12
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User entered '1'	System	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User entered '1'	System	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:08
User entered '804 (804)'	System	09 Feb 2021 20:10:10

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Feb 2021 12:09:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Feb 2021 12:09:46
Data point term sent to Coder	System	09 Feb 2021 20:11:21
User entered 'Prednisone'	Whitney West (b) (4)	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:20
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:25
User entered 'Adult respiratory distress syndrome'	Whitney West (b) (4)	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:27
User entered '30'	Whitney West (b) (4)	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:30
User entered 'mg (mg)'	Whitney West (b) (4)	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:32
User entered empty.	Whitney West (b) (4)	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:37
User entered 'once daily (QD)'	Whitney West (b) (4)	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:39
User entered empty.	Whitney West (b) (4)	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:41
User entered 'Oral (ORAL)'	Whitney West (b) (4)	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:44
User entered empty.	Whitney West (b) (4)	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 11:38:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:51
Query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' answered with 'Prednisone was being taken continuously, the window fits into titration schedule.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 20:00:20
User opened query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:45:06
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:40:30
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:01:02
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:49:45

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Jan 2021'	Whitney West (b) (4) (b) (4)	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:58:56
User entered '0'	Whitney West (b) (4)	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:34
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:38
User entered '30 Jan 2021'	Whitney West (b) (4)	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:01:42
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User entered '1'	System	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User entered '1'	System	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:21
User entered '804 (804)'	System	09 Feb 2021 20:11:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 12:09:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 12:09:47
Data point term sent to Coder	System	09 Feb 2021 20:12:23
User entered 'Prednisone'	Whitney West (b) (4) (b) (4)	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:20
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:22
User entered 'Adult respiratory distress syndrome'	Whitney West (b) (4)	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:25
User entered '20'	Whitney West (b) (4)	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:27
User entered 'mg (mg)'	Whitney West (b) (4)	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:30
User entered empty.	Whitney West (b) (4)	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:32
User entered 'once daily (QD)'	Whitney West (b) (4)	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:35
User entered empty.	Whitney West (b) (4)	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:37
User entered 'Oral (ORAL)'	Whitney West (b) (4)	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:58:39
User entered empty.	Whitney West (b) (4)	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 11:39:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:59:01
Query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' answered with 'Prednisone was being taken continuously, the window fits into titration schedule.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 20:01:14
User opened query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:44:24
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:44:24
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:01:31
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:57:51

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '31 Jan 2021'	Whitney West (b) (4) (b) (4)	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:59:07
User entered '0'	Whitney West (b) (4)	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:59:10
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:59:13
User entered '07 Feb 2021'	Whitney West (b) (4)	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:59:21
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User entered '1'	System	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User entered '1'	System	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:57:30
User entered '804 (804)'	System	09 Feb 2021 20:12:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:55:44
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #89. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:48:49
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #89. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:01:56
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #89. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:38:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: IPRATROPIUM/ALBUTEROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Feb 2021 13:16:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	11 Feb 2021 13:16:55

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	09 Feb 2021 20:16:28
User entered 'ipratropium-albuterol'	Whitney West (b) (4)	09 Feb 2021 20:15:48
	(b) (4)	

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:55:39
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 20:15:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:55:41
User entered 'COVID-19, adult respiratory distress syndrome'	Whitney West (b) (4)	09 Feb 2021 20:15:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:55:26
User entered '0.5-2.5/3'	Whitney West (b) (4)	09 Feb 2021 20:15:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:55:27
User entered 'Other (OTHER)'	Whitney West (b) (4)	09 Feb 2021 20:15:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:55:29
User entered 'mg/ml'	Whitney West (b) (4)	09 Feb 2021 20:15:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:55:32
User entered 'as needed (PRN)'	Whitney West (b) (4)	09 Feb 2021 20:15:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:55:36
User entered empty.	Whitney West (b) (4)	09 Feb 2021 20:15:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:55:23
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Whitney West (b) (4)	09 Feb 2021 20:15:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:55:21
User entered empty.	Whitney West (b) (4)	09 Feb 2021 20:15:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:55:19
User entered '01 Dec 2020'	Whitney West (b) (4)	09 Feb 2021 20:15:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:55:16
User entered '0'	Whitney West (b) (4)	09 Feb 2021 20:15:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:55:14
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:46:07
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:02:15
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:39:06
User entered 'Yes (Y)'	Whitney West (b) (4)	09 Feb 2021 20:15:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:55:12
User entered empty.	Whitney West (b) (4)	09 Feb 2021 20:15:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:55:10
User entered 'No (N)'	Whitney West (b) (4)	09 Feb 2021 20:15:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	09 Feb 2021 20:15:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	09 Feb 2021 20:15:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	09 Feb 2021 20:15:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:19:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 07:11:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 07:11:46
Data point term sent to Coder	System	17 Feb 2021 15:31:43
User entered 'Amoxicillin'	Whitney West (b) (4)	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:19:49
User entered 'Yes (Y)'	Whitney West (b) (4)	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:19:52
User entered 'Rhino rocket packing prophylaxis'	Whitney West (b) (4)	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:19:53
User closed query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' (Site from DM).		22 Mar 2021 14:49:42
User entered '500' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 22:03:18
Query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' answered with 'per subject data correct' (Site from DM).		19 Mar 2021 22:03:10
User opened query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:12:17
User entered '500 mg'	Whitney West (b) (4)	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:19:56
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:20:00
User entered empty.	Whitney West (b) (4)	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:20:02
User entered 'twice daily (BID)'	Whitney West (b) (4)	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:20:04
User entered empty.	Whitney West (b) (4)	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:20:08
User entered 'Oral (ORAL)'	Whitney West (b) (4)	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:20:11
User entered empty.	Whitney West (b) (4)	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:20:14
User entered '11 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:20:16
User entered '0'	Whitney West (b) (4)	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:20:19
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:20:22
User entered '13 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:20:24
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User entered '2'	System	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User entered '1'	System	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:58:31
User entered '804 (804)'	System	17 Feb 2021 15:30:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:21:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 15:34:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 15:34:02
Data point term sent to Coder	System	17 Feb 2021 15:32:44
User entered 'Quetiapine'	Whitney West (b) (4)	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:21:44
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:28:27
User entered 'Delirium'	Whitney West (b) (4)	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:28:30
User entered '25'	Whitney West (b) (4)	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:28:32
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:28:35
User entered empty.	Whitney West (b) (4)	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:28:37
User entered 'as needed (PRN)'	Whitney West (b) (4)	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:28:39
User entered empty.	Whitney West (b) (4)	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:28:40
User entered 'Oral (ORAL)'	Whitney West (b) (4)	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:33:24
User entered empty.	Whitney West (b) (4)	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:33:27
User entered '20 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:33:32
User entered '0'	Whitney West (b) (4)	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:33:35
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:33:37
User entered '30 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:33:41
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User entered empty.	System	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User entered empty.	System	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:02:54
User entered empty.	System	17 Feb 2021 15:32:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:33:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 07:21:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 07:21:46
Data point term sent to Coder	System	17 Feb 2021 16:56:30
User entered 'aspirin'	Whitney West (b) (4)	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:33:58
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:34:01
User entered 'Left lower leg deep vein thrombosis, extracorporeal membrane oxygenation'	Whitney West (b) (4)	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:34:05
User entered '81'	Whitney West (b) (4)	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:34:11
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:34:13
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:34:16
User entered 'once daily (QD)'	Whitney West (b) (4)	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:34:20
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:34:24
User entered 'Oral (ORAL)'	Whitney West (b) (4)	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:34:27
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:34:29
User entered '08 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:34:31
User entered '0'	Whitney West (b) (4)	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:34:34
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:34:36
User entered '12 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:34:46
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User entered '1'	System	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User entered '1'	System	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:06
User entered '804 (804)'	System	17 Feb 2021 16:55:30

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:39:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: AMINOGLYCOSIDE ANTIBACTERIALS, ATC: OTHER AMINOGLYCOSIDES, PRODUCT: TOBRAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:29:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:29:59
Data point term sent to Coder	System	17 Feb 2021 16:59:32
User entered 'Tobramycin'	Whitney West (b) (4) (b) (4)	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:39:29
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:39:31
User entered 'Adult respiratory distress syndrome, vancomycin-resistant enterococcus septicemia'	Whitney West (b) (4)	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:39:35
User entered '300'	Whitney West (b) (4)	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:39:37
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:39:39
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:39:42
User entered 'twice daily (BID)'	Whitney West (b) (4)	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:39:48
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:39:50
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Whitney West (b) (4) (b) (4)	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:39:53
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:39:56
User entered '04 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:39:58
User entered '0'	Whitney West (b) (4)	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:40:02
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:40:05
User entered '12 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:40:08
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User entered '2'	System	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User entered '1'	System	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:09
User entered '804 (804)'	System	17 Feb 2021 16:58:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
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)	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)	19 Apr 2021 11:19:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:44:03
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)	25 Mar 2021 05:27:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 05:27:48
Data point term sent to Coder	System	24 Mar 2021 19:26:53
Coding entries removed.	Whitney West (b) (4)	24 Mar 2021 19:26:44
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #91. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 12:54:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #91. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:03:39
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #91. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.	(b) (4), (b) (6)	02 Mar 2021 16:48:49
' (Site from DM). 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)	18 Feb 2021 09:19:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 09:19:48
Data point term sent to Coder	System	17 Feb 2021 17:19:57
User entered 'Potassium Chloride'	Whitney West (b) (4)	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:44:06
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:44:09
User closed query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that POTASSIUM CHLORIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:26:03
Query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that POTASSIUM CHLORIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. ' answered with 'Updated for indication. ' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:26:56
User entered 'Secondary to diuretic usage secondary to extracorporeal membranous oxygenation secondary to adult respiratory distress syndrome' reason for change: Per Query Resolution	Whitney West (b) (4)	24 Mar 2021 19:26:44
User opened query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that POTASSIUM CHLORIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:00:51
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:00:51

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:03:49
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).		02 Mar 2021 16:49:00
User entered 'Secondary to diuretics'	Whitney West (b) (4)	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:44:12
User entered '40'	Whitney West (b) (4)	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:44:15
User entered 'Other (OTHER)'	Whitney West (b) (4)	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:44:16
User entered 'mEq'	Whitney West (b) (4)	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:44:18
User entered 'as needed (PRN)'	Whitney West (b) (4)	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:44:21
User entered empty.	Whitney West (b) (4)	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:44:22
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:44:24
User entered empty.	Whitney West (b) (4)	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:44:29
User entered '05 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:44:31
User entered '0'	Whitney West (b) (4)	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:44:33
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:44:35
User entered '20 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:44:38
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User entered empty.	System	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User entered empty.	System	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:25
User entered empty.	System	17 Feb 2021 17:19:19

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:50:09
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #s 4 and 30. Please reconcile and update so there is no overlap. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:03:54
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #s 4 and 30. Please reconcile and update so there is no overlap. Otherwise, clarify. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:04:08
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #s 4 and 30. Please reconcile and update so there is no overlap. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:14:14
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 22:54:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 22:54:08
Data point term sent to Coder	System	17 Feb 2021 17:58:49
User entered 'Dexamethasone'	Whitney West (b) (4)	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:51:32
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:51:34
User entered 'Adult respiratory distress syndrome'	Whitney West (b) (4)	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:51:37
User entered '10'	Whitney West (b) (4)	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:51:38
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:51:42
User entered empty.	Whitney West (b) (4)	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:51:44
User entered 'once daily (QD)'	Whitney West (b) (4)	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:51:48
User entered empty.	Whitney West (b) (4)	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:51:51
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:52:05
User entered empty.	Whitney West (b) (4)	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:52:09
User entered '01 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:52:11
User entered '0'	Whitney West (b) (4)	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:52:15
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:52:17
User entered '11 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:52:20
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User entered '1'	System	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User entered '1'	System	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:31
User entered '804 (804)'	System	17 Feb 2021 17:58:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:56:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: HYOSCINE, PRODUCTSYNONYM: SCOPOLAMINE [HYOSCINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Mar 2021 11:30:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Mar 2021 11:30:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: BELLADONNA AND DERIVATIVES, PLAIN, ATC: BELLADONNA ALKALOIDS, SEMISYNTHETIC, QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: HYOSCINE, PRODUCTSYNONYM: SCOPOLAMINE [HYOSCINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Mar 2021 11:06:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Mar 2021 11:06:49
Data point term sent to Coder	System	17 Feb 2021 18:02:08
User entered 'Scopolamine patch'	Whitney West (b) (4)	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:56:55
User entered 'Yes (Y)'	Whitney West (b) (4)	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:56:56
User closed query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:05:39
Query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:04:47
User opened query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:58:39
User entered 'Postoperative nausea/vomiting'	Whitney West (b) (4)	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:57:01
User entered 'l'	Whitney West (b) (4)	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:57:03
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:57:07
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:57:46
User entered 'other (OTHER)'	Whitney West (b) (4)	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:57:50
User entered 'once per 72 hours'	Whitney West (b) (4)	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:57:54
User entered 'Transdermal (TRANSDERMAL)'	Whitney West (b) (4)	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:57:56
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:57:59
User entered '12 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:58:01
User entered '0'	Whitney West (b) (4)	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:58:04
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:58:06
User entered '12 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:58:08
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User entered empty.	System	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User entered empty.	System	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:34
User entered empty.	System	17 Feb 2021 18:01:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:00:31
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #106. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:06:39
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #106. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:05:04
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #106. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:41:48
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 07:00:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 07:00:12

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	17 Feb 2021 18:05:19
User entered 'Methylprednisolone'	Whitney West (b) (4)	17 Feb 2021 18:05:07
	(b) (4)	

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:00:35
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:00:37
User entered 'Multifocal pneumonia, adult respiratory distress syndrome'	Whitney West (b) (4)	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:00:38
User entered '125'	Whitney West (b) (4)	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:00:41
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:00:44
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:00:46
User entered 'four times daily (QID)'	Whitney West (b) (4)	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:00:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:00:53
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:00:55
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:00:58
User entered '25 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:01:00
User entered '0'	Whitney West (b) (4)	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:01:03
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:01:08
User entered '03 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:01:12
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User entered '4'	System	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User entered '1'	System	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:03:56
User entered '804 (804)'	System	17 Feb 2021 18:05:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:05:21
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)	25 Mar 2021 04:48:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 04:48:49
Data point term sent to Coder	System	24 Mar 2021 19:37:06
Coding entries removed.	Whitney West (b) (4)	24 Mar 2021 19:36:49
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)	17 Feb 2021 18:24:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 18:24:23
Data point term sent to Coder	System	17 Feb 2021 18:06:18
User entered 'Oxycodone'	Whitney West (b) (4)	17 Feb 2021 18:06:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:05:23
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:05:26
User closed query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:26:44
User closed query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:26:42
Query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' answered with 'AE updated.' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:37:03
Query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'AE updated.' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:36:57
User entered 'PAIN, Generalized' reason for change: Per Query Resolution	Whitney West (b) (4)	24 Mar 2021 19:36:49
User opened query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:42:16
User opened query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:41:59

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:41:59
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	19 Mar 2021 22:05:22
' answered with 'per subject data correct' (Site from DM).		
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	02 Mar 2021 16:46:21
' (Site from DM).		
User entered 'Pain'	Whitney West (b) (4)	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:05:31
User entered '5'	Whitney West (b) (4)	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:05:39
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:05:42
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:05:46
User entered 'as needed (PRN)'	Whitney West (b) (4)	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:05:48
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:05:51
User entered 'Oral (ORAL)'	Whitney West (b) (4)	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:05:54
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:05:57
User entered '25 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:01
User entered '0'	Whitney West (b) (4)	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:03
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 18:06:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 18:06:19
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	17 Feb 2021 18:06:19
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 18:06:14
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:07
User entered '09 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:10
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User entered empty.	System	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User entered empty.	System	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:10
User entered empty.	System	17 Feb 2021 18:06:14

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:07:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 18:22:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 18:22:11
Data point term sent to Coder	System	17 Feb 2021 18:08:20
User entered 'Bisacodyl'	Whitney West (b) (4)	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:07:31
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:07:33
User entered 'Constipation'	Whitney West (b) (4)	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:07:35
User entered '10'	Whitney West (b) (4)	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:07:38
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:07:40
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:07:44
User entered 'as needed (PRN)'	Whitney West (b) (4)	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:07:47
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:07:51
User entered 'Rectal (RECTAL)'	Whitney West (b) (4)	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:07:54
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:07:57
User entered '01 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:07:59
User entered '0'	Whitney West (b) (4)	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:08:02
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:08:05
User entered '20 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:08:08
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User entered empty.	System	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User entered empty.	System	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:14
User entered empty.	System	17 Feb 2021 18:07:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:08:20
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, PRODUCT: ACETAZOLAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 08:22:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 08:22:50
Data point term sent to Coder	System	24 Mar 2021 19:53:23
Coding entries removed.	Whitney West (b) (4)	24 Mar 2021 19:52:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, PRODUCT: ACETAZOLAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 06:54:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 06:54:46
Data point term sent to Coder	System	17 Feb 2021 18:09:25
User entered 'Acetazolamide'	Whitney West (b) (4)	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:08:24
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:08:28
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame (ADULT RESPIRATORY DISTRESS SYNDROME End date 20 JAN 2021). Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).		07 Apr 2021 11:48:15
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame (ADULT RESPIRATORY DISTRESS SYNDROME End date 20 JAN 2021). Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Wrong month input. ' (Site from DM).	Whitney West (b) (4)	06 Apr 2021 18:14:19
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame (ADULT RESPIRATORY DISTRESS SYNDROME End date 20 JAN 2021). Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 03:39:59
User closed query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that ACETAZOLAMIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).		25 Mar 2021 08:27:15

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that ACETAZOLAMIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'Updated per query. ' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:52:41
User entered 'EXTRACORPOREAL MEMBRANE OXYGENATION secondary to adult respiratory distress syndrome' reason for change: Data Entry Error	Whitney West (b) (4)	24 Mar 2021 19:52:22
User opened query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that ACETAZOLAMIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:07:50
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:07:50
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:05:41
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:10:38
User entered 'Extracorporeal membrane oxygenation'	Whitney West (b) (4)	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:08:35
User entered '250'	Whitney West (b) (4)	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:08:38
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:08:40
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:08:42
User entered 'twice daily (BID)'	Whitney West (b) (4)	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:08:45
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:08:48
User entered 'Oral (ORAL)'	Whitney West (b) (4)	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:08:51
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:09:37
User entered '12 Jan 2021' reason for change: Data Entry Error	Whitney West (b) (4)	06 Apr 2021 18:14:09
User entered '12 Feb 2021'	Whitney West (b) (4)	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:09:44
User entered '0'	Whitney West (b) (4)	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:09:46
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:09:50
User entered '12 Jan 2021' reason for change: Data Entry Error	Whitney West (b) (4)	06 Apr 2021 18:14:09
User entered '12 Feb 2021'	Whitney West (b) (4)	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:09:53
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User entered '2'	System	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User entered '1'	System	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:48
User entered '804 (804)'	System	17 Feb 2021 18:08:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:09:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:03:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:03:23
Data point term sent to Coder	System	24 Mar 2021 19:51:21
Coding entries removed.	Whitney West (b) (4)	24 Mar 2021 19:50:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 08:19:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 08:19:52
Data point term sent to Coder	System	17 Feb 2021 18:10:26
User entered 'Fentanyl patch'	Whitney West (b) (4)	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:10:01
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:10:03
User closed query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:27:39
User closed query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRF's as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:27:37
Query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' answered with 'AE updated. ' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:51:39
Query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRF's as appropriate.' answered with 'AE updated. ' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:51:33
User entered 'PAIN, Generalized' reason for change: Data Entry Error	Whitney West (b) (4)	24 Mar 2021 19:50:57
User opened query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:39:57
User opened query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRF's as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:39:27

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:39:27
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	19 Mar 2021 22:06:02
' answered with 'per subject data correct' (Site from DM).		
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	02 Mar 2021 16:30:30
' (Site from DM).		
User entered 'Pain'	Whitney West (b) (4)	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:10:10
User entered '75'	Whitney West (b) (4)	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:10:13
User entered 'Other (OTHER)'	Whitney West (b) (4)	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:10:16
User entered 'mcg'	Whitney West (b) (4)	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:10:20
User entered 'other (OTHER)'	Whitney West (b) (4)	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:10:22
User entered 'Q72 hours'	Whitney West (b) (4)	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:10:25
User entered 'Topical (TOPICAL)'	Whitney West (b) (4)	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:10:29
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:10:34
User entered '17 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:10:36
User entered '0'	Whitney West (b) (4)	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:10:41
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:10:45
User entered '28 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:10:48
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User entered empty.	System	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User entered empty.	System	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:04:59
User entered empty.	System	17 Feb 2021 18:10:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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)	20 Feb 2021 14:24:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 14:24:48
Data point term sent to Coder	System	17 Feb 2021 18:11:33
User entered 'Melatonin'	Whitney West (b) (4)	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Insomnia, Delirium'	Whitney West (b) (4)	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '9'	Whitney West (b) (4)	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once daily (QD)'	Whitney West (b) (4)	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '25 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Yes (Y)'	Whitney West (b) (4)	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	17 Feb 2021 18:11:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: KETAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 12:19:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 12:19:30
Data point term sent to Coder	System	24 Mar 2021 19:42:13
Coding entries removed.	Whitney West (b) (4)	24 Mar 2021 19:41:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: KETAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 08:22:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 08:22:50
Data point term sent to Coder	System	17 Feb 2021 18:13:35
User entered 'Ketamine'	Whitney West (b) (4)	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that KETAMINE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:28:26
Query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that KETAMINE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'Updated per query.' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:41:54
User entered 'EXTRACORPOREAL MEMBRANE OXYGENATION secondary to adult respiratory syndrome, DELIRIUM secondary to sedation secondary to adult respiratory syndrome' reason for change: Data Entry Error	Whitney West (b) (4)	24 Mar 2021 19:41:40
User opened query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that KETAMINE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:09:00
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 EXTRACORPOREAL MEMBRANE OXYGENATION. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:09:00

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead EXTRACORPOREAL MEMBRANE OXYGENATION. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:06:22
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 EXTRACORPOREAL MEMBRANE OXYGENATION. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:39:44
User entered 'Extracorporeal membrane oxygenation, Whitney West Delirium'	(b) (4)	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0.05-1.00'	Whitney West (b) (4)	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Other (OTHER)'	Whitney West (b) (4)	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the unit and frequency recorded as these reflects the rate of infusion rather than the unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM). Query 'Per DM CLR: Please review the unit and frequency recorded as these reflects the rate of infusion rather than the unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:47:17
User opened query 'Per DM CLR: Please review the unit and frequency recorded as these reflects the rate of infusion rather than the unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:06:29
User entered 'mg/kg'	Whitney West (b) (4)	02 Mar 2021 16:39:51
	(b) (4)	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'other (OTHER)'	Whitney West (b) (4)	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '/hour'	Whitney West (b) (4)	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Whitney West (b) (4)	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '25 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User entered empty.	System	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User entered empty.	System	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:15
User entered empty.	System	17 Feb 2021 18:13:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: IPRATROPIUM/ALBUTEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 14:01:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 14:01:44
Data point term sent to Coder	System	17 Feb 2021 18:14:37
User entered 'ipratropium-albuterol'	Whitney West (b) (4)	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Adult respiratory distress syndrome'	Whitney West (b) (4)	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of mL count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 14:48:59
Query 'Per DM CLR: Please provide the actual dose for this medication instead of mL count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:06:49
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of mL count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:38:39
User entered '3'	Whitney West (b) (4)	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mL (mL)'	Whitney West (b) (4)	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'other (OTHER)'	Whitney West (b) (4)	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Q4hours'	Whitney West (b) (4)	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Whitney West (b) (4) (b) (4)	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '01 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User entered empty.	System	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User entered empty.	System	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (89)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:27
User entered empty.	System	17 Feb 2021 18:14:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: CRIES PROPHYLACTIC AGENTS, PRODUCT: SODIUM FLUOROPHOSPHATE, PRODUCTSYNONYM: SODIUM MONOFLUOROPHOSPHATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Mar 2021 16:07:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Mar 2021 16:07:57
Data point term sent to Coder	System	18 Feb 2021 14:03:24
User closed query 'DM-Coding: please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	18 Feb 2021 14:03:18
Query 'DM-Coding: please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'Updated with active ingredient' (Site from System).	Whitney West (b) (4)	18 Feb 2021 14:03:18
User entered 'BIOTENE (sodium monofluorophosphate)' reason for change: Data Entry Error	Whitney West (b) (4)	18 Feb 2021 14:02:57
User opened query 'DM-Coding: please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4)	18 Feb 2021 07:46:46
Data point term sent to Coder	System	17 Feb 2021 18:15:38
User entered 'Biotine'	Whitney West (b) (4)	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral ulcerations'	Whitney West (b) (4)	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0.125-0.25'	Whitney West (b) (4)	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mL (mL)'	Whitney West (b) (4)	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'as needed (PRN)'	Whitney West (b) (4)	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '26 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:33:02
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:07:07
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:13:17
User entered 'Yes (Y)'	Whitney West (b) (4)	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (90)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	17 Feb 2021 18:15:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 05:29:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 05:29:00
Data point term sent to Coder	System	24 Mar 2021 19:40:10
Coding entries removed.	Whitney West (b) (4)	24 Mar 2021 19:39:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 09:18:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 09:18:49
Data point term sent to Coder	System	17 Feb 2021 18:16:40
User entered 'Potassium Chloride'	Whitney West (b) (4)	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that POTASSIUM CHLORIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).		25 Mar 2021 08:28:44
Query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that POTASSIUM CHLORIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'Updated.' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:39:20
User entered 'EXTRACORPOREAL MEMBRANE OXYGENATION secondary to adult respiratory distress syndrome' reason for change: Per Query Resolution	Whitney West (b) (4)	24 Mar 2021 19:39:13
User opened query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that POTASSIUM CHLORIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:10:03
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:10:03

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:07:28
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:48:33
User entered 'Extracorporeal membrane oxygenation' Whitney West	(b) (4)	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '30'	Whitney West (b) (4)	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Other (OTHER)'	Whitney West (b) (4)	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mEq'	Whitney West (b) (4)	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'as needed (PRN)'	Whitney West (b) (4)	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '02 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '28 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User entered empty.	System	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User entered empty.	System	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (91)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:05:51
User entered empty.	System	17 Feb 2021 18:16:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: LINEZOLID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 14:10:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 14:10:45
Data point term sent to Coder	System	17 Feb 2021 18:18:42
User entered 'Linezolid'	Whitney West (b) (4)	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Vancomycin-resistant enterococcus septicemia, ventilator associated pneumonia, pseudomonas bilateral'	Whitney West (b) (4)	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '600'	Whitney West (b) (4)	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'twice daily (BID)'	Whitney West (b) (4)	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '02 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '02 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User entered '2'	System	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User entered '1'	System	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (92)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:04
User entered '804 (804)'	System	17 Feb 2021 18:18:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #18. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:11:00
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #18. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:07:47
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #18. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:41:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: CARBAPENEMS, PRODUCT: MEROPENEM TRIHYDRATE, PRODUCTSYNONYM: MERREM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 19:56:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 19:56:03
Data point term sent to Coder	System	17 Feb 2021 19:55:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Merrem'	Whitney West (b) (4) (b) (4)	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Adult respiratory distress syndrome'	Whitney West (b) (4)	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '500'	Whitney West (b) (4)	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'four times daily (QID)'	Whitney West (b) (4)	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '28 Nov 2020'	Whitney West (b) (4)	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '03 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User entered '4'	System	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User entered '1'	System	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (93)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:09
User entered '804 (804)'	System	17 Feb 2021 19:55:22

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 12:25:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 12:25:26
Data point term sent to Coder	System	24 Mar 2021 19:39:10
Coding entries removed.	Whitney West (b) (4) (b) (4)	24 Mar 2021 19:38:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 08:19:53
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 Feb 2021 08:19:53
Data point term sent to Coder	System	17 Feb 2021 19:57:37
User entered 'Furosemide'	Whitney West (b) (4) (b) (4)	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per CDM: Response noted. Please consider to update 'indication' as per your previous response due to 'ARDS' . Ensure to expand the meaning of 'ARDS' rather to use abbreviations and reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:29:01
Query 'Per CDM: Response noted. Please consider to update 'indication' as per your previous response due to 'ARDS' . Ensure to expand the meaning of 'ARDS' rather to use abbreviations and reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'Updated.' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:38:17
User entered 'EXTRACORPOREAL MEMBRANE OXYGENATION secondary to Adult respiratory distress syndrome' reason for change: Data Entry Error	Whitney West (b) (4)	24 Mar 2021 19:38:08
User opened query 'Per CDM: Response noted. Please consider to update 'indication' as per your previous response due to 'ARDS' . Ensure to expand the meaning of 'ARDS' rather to use abbreviations and reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:20:54
User closed query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that FUROSEMIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:20:54

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that FUROSEMIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'The fluid status was being addressed due to the participant being on ECMO. Participant is on ECMO due to ARDS. Should the ECMO be replaced with ARDS then? ' (Site from DM).	Whitney West (b) (4)	23 Mar 2021 18:12:44
User opened query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that FUROSEMIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:11:38
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	23 Mar 2021 13:11:38
' (Site from DM).		
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	19 Mar 2021 22:08:09
' answered with 'per subject data correct' (Site from DM).		
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.	(b) (4), (b) (6)	02 Mar 2021 16:32:28
' (Site from DM).		

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
User entered 'Extracorporeal membrane oxygenation'	Whitney West (b) (4)	17 Feb 2021 19:57:06
	(b) (4)	

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20'	Whitney West (b) (4)	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'twice daily (BID)'	Whitney West (b) (4)	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '01 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '01 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User entered '2'	System	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User entered '1'	System	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (94)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:25
User entered '804 (804)'	System	17 Feb 2021 19:57:06

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 09:21:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 09:21:50
Data point term sent to Coder	System	24 Mar 2021 19:36:06
Coding entries removed.	Whitney West (b) (4)	24 Mar 2021 19:35:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 19:59:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 19:59:03
Data point term sent to Coder	System	17 Feb 2021 19:58:40
User entered 'Morphine'	Whitney West (b) (4)	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:29:19
User closed query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:29:17
Query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'AE was updated.' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:35:34
Query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' answered with 'AE updated.' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:35:20
User entered 'PAIN, Generalized' reason for change: Per Query Resolution	Whitney West (b) (4)	24 Mar 2021 19:35:06
User opened query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:41:40
User opened query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:41:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:41:26
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	19 Mar 2021 22:08:31
' answered with 'per subject data correct' (Site from DM).		
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	02 Mar 2021 16:45:14
' (Site from DM).		
User entered 'Pain'	Whitney West (b) (4)	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '10'	Whitney West (b) (4)	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'other (OTHER)'	Whitney West (b) (4)	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Q4hours'	Whitney West (b) (4)	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '28 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User entered empty.	System	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User entered empty.	System	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (95)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:06:56
User entered empty.	System	17 Feb 2021 19:57:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: FENTANYL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 14:03:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 14:03:23
Data point term sent to Coder	System	24 Mar 2021 19:32:03
Coding entries removed.	Whitney West (b) (4)	24 Mar 2021 19:31:41
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #27. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:12:31
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #27. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:08:52
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #27. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:30:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 08:19:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 08:19:53
Data point term sent to Coder	System	17 Feb 2021 19:59:40
User entered 'Fentanyl patch'	Whitney West (b) (4)	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:30:23
User closed query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 08:30:21
Query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' answered with 'AE has updated.' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:32:11
Query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'AE has been updated.' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:32:04
User entered 'PAIN, Generalized' reason for change: Per Query Resolution	Whitney West (b) (4)	24 Mar 2021 19:31:41
User opened query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:40:55
User opened query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:40:37

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:40:37
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:09:00
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:30:59
User entered 'Pain'	Whitney West (b) (4)	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '100'	Whitney West (b) (4)	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Other (OTHER)'	Whitney West (b) (4)	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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), (b) (6)	22 Mar 2021 18:47:01
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 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:09:05
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)	02 Mar 2021 16:31:08
User entered 'mcg/hr/patch'	Whitney West (b) (4) (b) (4)	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'other (OTHER)'	Whitney West (b) (4)	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Q72hours'	Whitney West (b) (4)	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Topical (TOPICAL)'	Whitney West (b) (4)	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '25 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '17 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User entered empty.	System	17 Feb 2021 19:59:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User entered empty.	System	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (96)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:09
User entered empty.	System	17 Feb 2021 19:59:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 23:05:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 23:05:08
Data point term sent to Coder	System	17 Feb 2021 23:03:50
User entered 'Amlodipine'	Whitney West (b) (4)	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:02:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Hypertension'	Whitney West (b) (4)	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '5'	Whitney West (b) (4)	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:02:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once daily (QD)'	Whitney West (b) (4)	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '21 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Yes (Y)'	Whitney West (b) (4)	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (97)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	17 Feb 2021 23:02:53

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN HUMAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 11:21:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 11:21:26
Data point term sent to Coder	System	24 Mar 2021 19:31:02
Coding entries removed.	Whitney West (b) (4)	24 Mar 2021 19:30:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN HUMAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 17:18:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 17:18:52
Data point term sent to Coder	System	17 Feb 2021 23:05:52
User entered 'Albumin human 25%'	Whitney West (b) (4)	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that ALBUMIN HUMAN 25% is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).		25 Mar 2021 08:30:44
Query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that ALBUMIN HUMAN 25% is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'Updated.' (Site from DM).	Whitney West (b) (4)	24 Mar 2021 19:32:42
User entered 'Altered fluid status secondary to EXTRACORPOREAL MEMBRANE OXYGENATION secondary to adult respiratory distress syndrome' reason for change: Per Query Resolution	Whitney West (b) (4)	24 Mar 2021 19:30:53
User opened query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that ALBUMIN HUMAN 25% is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:13:17
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:13:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:09:24
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:11:11
User entered 'Extracorporeal membrane oxygenation' Whitney West	(b) (4)	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '25/100'	Whitney West (b) (4)	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Other (OTHER)'	Whitney West (b) (4)	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'g/mL'	Whitney West (b) (4)	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'as needed (PRN)'	Whitney West (b) (4)	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '02 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '31 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User entered empty.	System	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User entered empty.	System	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (98)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:15
User entered empty.	System	17 Feb 2021 23:05:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 08:58:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 08:58:35
Data point term sent to Coder	System	23 Mar 2021 18:16:30
Coding entries removed.	Whitney West (b) (4)	23 Mar 2021 18:15:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 23:09:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 23:09:05
Data point term sent to Coder	System	17 Feb 2021 23:07:52
User entered 'Tramadol'	Whitney West (b) (4)	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:22:54
User closed query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 09:22:46
Query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' answered with 'Updated.' (Site from DM).	Whitney West (b) (4)	23 Mar 2021 18:16:02
Query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate' answered with 'The medical record indicated generalized pain.' (Site from DM).	Whitney West (b) (4)	23 Mar 2021 18:15:56
User entered 'PAIN, Generalized' reason for change: Data Entry Error	Whitney West (b) (4)	23 Mar 2021 18:15:33
User opened query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:43:18
User opened query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:43:05

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:43:05
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	19 Mar 2021 22:09:42
' answered with 'per subject data correct' (Site from DM).		
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	02 Mar 2021 16:59:56
' (Site from DM).		
User entered 'Pain'	Whitney West (b) (4)	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '50'	Whitney West (b) (4)	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'as needed (PRN)'	Whitney West (b) (4)	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '10 Feb 2021'	Whitney West (b) (4)	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User entered empty.	System	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User entered empty.	System	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (99)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:41
User entered empty.	System	17 Feb 2021 23:07:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, as there are multiple dosage options for this drug. Review and amend as appropriate. ' (Site from DM).		23 Mar 2021 13:14:52
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, as there are multiple dosage options for this drug. Review and amend as appropriate. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:10:00
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, as there are multiple dosage options for this drug. Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:58:54
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTISEPTICS AND DISINFECTANTS, ATC: ANTISEPTICS AND DISINFECTANTS, ATC: SILVER COMPOUNDS, PRODUCT: SILVER NITRATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Mar 2021 07:28:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	02 Mar 2021 07:28:10
Data point term sent to Coder	System	17 Feb 2021 23:09:53
User entered 'Silver nitrate'	Whitney West (b) (4)	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Right-sided epistaxis'	Whitney West (b) (4)	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'I'	Whitney West (b) (4)	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Other (OTHER)'	Whitney West (b) (4)	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'application'	Whitney West (b) (4)	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once (ONCE)'	Whitney West (b) (4)	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Topical (TOPICAL)'	Whitney West (b) (4)	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '12 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '12 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User entered empty.	System	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User entered empty.	System	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (100)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:07:55
User entered empty.	System	17 Feb 2021 23:09:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #51. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:16:30
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #51. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:10:24
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #51. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:44:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Feb 2021 14:27:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Feb 2021 14:27:48
Data point term sent to Coder	System	17 Feb 2021 23:15:00
User entered 'Metronidazole'	Whitney West (b) (4)	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Ventilator-associated pneumonia, pseudomonas bilateral'	Whitney West (b) (4)	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '500'	Whitney West (b) (4)	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'three times daily (TID)'	Whitney West (b) (4)	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:15:44
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:10:31
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:44:45
User entered '03 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '08 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User entered '3'	System	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User entered '1'	System	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (101)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:39
User entered '804 (804)'	System	17 Feb 2021 23:14:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 14:27:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 14:27:48
Data point term sent to Coder	System	17 Feb 2021 23:16:02
User entered 'Metronidazole'	Whitney West (b) (4)	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Ventilator-associated pneumonia, pseudomonas bilateral'	Whitney West (b) (4)	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '500'	Whitney West (b) (4)	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'three times daily (TID)'	Whitney West (b) (4)	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '18 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '22 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User entered '3'	System	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User entered '1'	System	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (102)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:43
User entered '804 (804)'	System	17 Feb 2021 23:15:12

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISOLONE, PRODUCTSYNONYM: DELTASONE [PREDNISOLONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 22:46:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 22:46:05
Data point term sent to Coder	System	17 Feb 2021 23:25:11
User entered 'Deltasone'	Whitney West (b) (4)	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Acute respiratory failure'	Whitney West (b) (4)	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '10'	Whitney West (b) (4)	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once daily (QD)'	Whitney West (b) (4)	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '18 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '21 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 23:24:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 23:24:59
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	17 Feb 2021 23:24:59
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 23:24:56
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:24:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User entered '1'	System	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User entered '1'	System	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (103)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:51
User entered '804 (804)'	System	17 Feb 2021 23:24:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #2. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:17:11
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #2. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:10:54
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #2. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:11:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 23:28:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 23:28:06
Data point term sent to Coder	System	17 Feb 2021 23:27:12
User entered 'Albuterol sulfate'	Whitney West (b) (4)	17 Feb 2021 23:26:55

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Covid-19'	Whitney West (b) (4)	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the dose and unit recorded as these are not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).		22 Mar 2021 18:34:38
Query 'Per DM CLR: Please review the dose and unit recorded as these are not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:10:59
User opened query 'Per DM CLR: Please review the dose and unit recorded as these are not the standard for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:11:32
User entered '2.5'	Whitney West (b) (4)	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'four times daily (QID)'	Whitney West (b) (4)	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Whitney West (b) (4) (b) (4)	17 Feb 2021 23:26:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '16 Nov 2020'	Whitney West (b) (4)	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User entered '4'	System	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User entered '1'	System	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (104)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:13:50
User entered '804 (804)'	System	17 Feb 2021 23:26:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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: OTHER NASAL PREPARATIONS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 09:20:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 09:20:29
Data point term sent to Coder	System	19 Mar 2021 22:11:44
User closed query ' DM-Coding: please split "OXYMETAZOLINE 0.025%/LIDOCAINE 2%" term into 2 separate entries. One drug per line. Please update this term in accordance with your answer.' (Site from System).	System	19 Mar 2021 22:11:18
Query ' DM-Coding: please split "OXYMETAZOLINE 0.025%/LIDOCAINE 2%" term into 2 separate entries. One drug per line. Please update this term in accordance with your answer.' answered with 'per subject data correct' (Site from System).	(b) (4), (b) (6)	19 Mar 2021 22:11:18
User opened query ' DM-Coding: please split "OXYMETAZOLINE 0.025%/LIDOCAINE 2%" term into 2 separate entries. One drug per line. Please update this term in accordance with your answer.' (Site from System).	Coder Import (b) (4)	19 Mar 2021 09:52:30
Data point term sent to Coder	System	18 Feb 2021 13:50:12
User entered 'Oxymetazoline 0.025%/Lidocaine 2%'	Whitney West (b) (4)	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Right-sided epistaxis'	Whitney West (b) (4)	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '1-2'	Whitney West (b) (4)	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Other (OTHER)'	Whitney West (b) (4)	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'sprays/nare'	Whitney West (b) (4)	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'as needed (PRN)'	Whitney West (b) (4)	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Nasal (NASAL)'	Whitney West (b) (4)	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:17:40
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:11:23
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:47:01
User entered '01 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '21 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User entered empty.	System	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User entered empty.	System	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (105)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:05
User entered empty.	System	18 Feb 2021 13:49:31

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Feb 2021 14:26:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Feb 2021 14:26:50
Data point term sent to Coder	System	18 Feb 2021 13:55:14
Data point term sent to Coder	System	18 Feb 2021 13:52:14
User entered 'Methylprednisolone'	Whitney West (b) (4)	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Adult respiratory distress syndrome' reason for change: Data Entry Error	Whitney West (b) (4)	18 Feb 2021 13:54:24
User entered '60'	Whitney West (b) (4)	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '60'	Whitney West (b) (4)	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'twice daily (BID)'	Whitney West (b) (4)	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '31 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '01 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User entered '2'	System	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User entered '1'	System	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (106)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:14:09
User entered '804 (804)'	System	18 Feb 2021 13:52:02

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Feb 2021 14:26:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Feb 2021 14:26:51
Data point term sent to Coder	System	18 Feb 2021 13:54:14
User entered 'Methylprednisolone'	Whitney West (b) (4)	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Adult respiratory distress syndrome'	Whitney West (b) (4)	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '30'	Whitney West (b) (4)	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'twice daily (BID)'	Whitney West (b) (4)	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '02 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '02 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User entered '2'	System	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User entered '1'	System	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (107)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:19
User entered '804 (804)'	System	18 Feb 2021 13:54:05

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 14:07:54
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 Feb 2021 14:07:54
Data point term sent to Coder	System	18 Feb 2021 14:07:26
User entered 'Hydralazine'	Whitney West (b) (4) (b) (4)	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Hypertension'	Whitney West (b) (4)	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20'	Whitney West (b) (4)	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'as needed (PRN)'	Whitney West (b) (4)	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:18:27
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. Otherwise, provide clarification for this occurrence. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:11:37
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. Otherwise, provide clarification for this occurrence. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:33:19
User entered '01 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '21 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User entered empty.	System	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User entered empty.	System	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (108)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:24
User entered empty.	System	18 Feb 2021 14:07:16

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 08:20:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 08:20:45
Data point term sent to Coder	System	18 Feb 2021 14:08:26
User entered 'Insulin lispro'	Whitney West (b) (4)	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Steroid-induced hyperglycemia'	Whitney West (b) (4)	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '3-21'	Whitney West (b) (4)	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Other (OTHER)'	Whitney West (b) (4)	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'units'	Whitney West (b) (4)	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'four times daily (QID)'	Whitney West (b) (4)	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Subcutaneous (SUBCUTANEOUS)'	Whitney West (b) (4)	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '02 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '28 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User entered '4'	System	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User entered '1'	System	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (109)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:15:36
User entered '804 (804)'	System	18 Feb 2021 14:08:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 14:53:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 14:53:51
Data point term sent to Coder	System	18 Feb 2021 14:52:59
User entered 'Metoprolol'	Whitney West (b) (4)	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Tachycardia'	Whitney West (b) (4)	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '25'	Whitney West (b) (4)	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'twice daily (BID)'	Whitney West (b) (4)	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '21 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Yes (Y)'	Whitney West (b) (4)	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '2'	System	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (110)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	18 Feb 2021 14:52:07

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #43 and #110. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:19:52
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #43 and #110. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:11:54
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #43 and #110. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:44:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 07:07:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 07:07:07
Data point term sent to Coder	System	18 Feb 2021 14:55:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'metoprolol tartrate'	Whitney West (b) (4) (b) (4)	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'tachycardia'	Whitney West (b) (4)	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '5'	Whitney West (b) (4)	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'as needed (PRN)'	Whitney West (b) (4)	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '31 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User entered empty.	System	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User entered empty.	System	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (111)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:32
User entered empty.	System	18 Feb 2021 14:54:08

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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)	30 Mar 2021 09:57:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 09:57:41
Data point term sent to Coder	System	29 Mar 2021 18:03:45
Coding entries removed.	Whitney West (b) (4)	29 Mar 2021 18:03:12
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #95. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:23:10
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #95. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' answered with 'information needs to be listed separately' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:12:35
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #95. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:45:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
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)	20 Feb 2021 14:29:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 14:29:46
Data point term sent to Coder	System	18 Feb 2021 14:56:03
User entered 'Morphine sulfate'	Whitney West (b) (4)	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:42:32
Query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'Unfortunately as these AEs and medications were recorded by hospital staff there is no way to get further information. The records were provided by the subject who cannot tell us and the hospital referred everything to legal and the nurses at the time called it generalized.' (Site from DM).	Whitney West (b) (4)	06 Apr 2021 15:48:31
User entered 'PAIN, generalized' reason for change: Data Entry Error	Whitney West (b) (4)	29 Mar 2021 18:03:12
User opened query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:22:51
User closed query ' Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:22:51
Query ' Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:12:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
User opened query ' Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:45:45
User entered 'Pain'	Whitney West (b) (4)	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '2-4'	Whitney West (b) (4)	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'as needed (PRN)'	Whitney West (b) (4)	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '28 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '28 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User entered empty.	System	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User entered empty.	System	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (112)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:37
User entered empty.	System	18 Feb 2021 14:55:41

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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)	06 Apr 2021 15:50:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Apr 2021 15:50:21
Data point term sent to Coder	System	06 Apr 2021 15:49:47
Coding entries removed.	Whitney West (b) (4)	06 Apr 2021 15:49:01
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #83. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:23:26
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #83. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' answered with 'information needs to be listed separately' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:13:11
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #83. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:46:39

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
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 Feb 2021 14:58:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 14:58:52
Data point term sent to Coder	System	18 Feb 2021 14:58:06
User entered 'Oxycodone'	Whitney West (b) (4)	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:45:51
User closed query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:45:27
Query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate' answered with 'Subject was sedated. Nurses from the hospital records recorded it only as 'generalized.' The records don't elaborate and the hospital has referred all further requests to their legal department with no further response. ' (Site from DM).	Whitney West (b) (4)	06 Apr 2021 15:52:15
Query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' answered with 'Generalized added. ' (Site from DM).	Whitney West (b) (4)	06 Apr 2021 15:49:27
User entered 'PAIN, Generalized' reason for change:	Whitney West (b) (4)	06 Apr 2021 15:49:01
Data Entry Error	(b) (4)	
User opened query 'Per CDM: Response does not satisfy query. Please update the 'Indication' (PAIN) to reflect the location/type of pain. Please reconcile with the AE and Med History eCRFs as appropriate' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:42:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:42:36
User closed query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:42:30
Query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:13:16
User opened query 'Per DM CLR: Please update the indication to reflect the location of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:46:47
User entered 'Pain'	Whitney West (b) (4)	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '5'	Whitney West (b) (4)	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'as needed (PRN)'	Whitney West (b) (4)	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '30 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '28 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User entered empty.	System	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User entered empty.	System	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (113)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:16:41
User entered empty.	System	18 Feb 2021 14:57:17

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #67. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:23:44
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #67. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' answered with 'information needs to be listed separately' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:13:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Mar 2021 05:29:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Mar 2021 05:29:48
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #67. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:58:26
Data point term sent to Coder	System	18 Feb 2021 15:26:36

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Quetiapine'	Whitney West (b) (4) (b) (4)	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Delirium/Insomnia'	Whitney West (b) (4)	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '75'	Whitney West (b) (4)	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'four times daily (QID)'	Whitney West (b) (4)	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '12 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User entered '4'	System	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User entered '1'	System	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (114)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:02
User entered '804 (804)'	System	18 Feb 2021 15:26:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #58. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:23:57
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #58. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' answered with 'information needs to be listed separately' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:14:19
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #58. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:15:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 15:25:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 15:25:52
Data point term sent to Coder	System	18 Feb 2021 15:25:36

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Docusate'	Whitney West (b) (4) (b) (4)	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Constipation'	Whitney West (b) (4)	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '50/5'	Whitney West (b) (4)	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Other (OTHER)'	Whitney West (b) (4)	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg/mL'	Whitney West (b) (4)	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once daily (QD)'	Whitney West (b) (4)	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '21 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '28 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User entered '1'	System	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User entered '1'	System	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (115)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:07
User entered '804 (804)'	System	18 Feb 2021 15:24:55

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #68. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:24:30
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #68. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' answered with 'information needs listed separately' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:15:22
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #68. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:49:20
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 07:31:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 07:31:08

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	18 Feb 2021 15:28:38
User entered 'Prednisone'	Whitney West (b) (4)	18 Feb 2021 15:28:04
	(b) (4)	

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:28:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Adult respiratory distress syndrome'	Whitney West (b) (4)	18 Feb 2021 15:28:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '50'	Whitney West (b) (4)	18 Feb 2021 15:28:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	18 Feb 2021 15:28:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:28:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once daily (QD)'	Whitney West (b) (4)	18 Feb 2021 15:28:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:28:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	18 Feb 2021 15:28:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:28:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '10 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 15:28:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 15:28:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:28:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '16 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 15:28:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:28:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User entered '1'	System	18 Feb 2021 15:28:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User entered '1'	System	18 Feb 2021 15:28:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (117)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:26
User entered '804 (804)'	System	18 Feb 2021 15:28:04

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #69. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:24:45
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #69. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' answered with 'information needs listed separately' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:15:57
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #69. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:49:30
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 07:31:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 07:31:08

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	18 Feb 2021 15:29:40
User entered 'Prednisone'	Whitney West (b) (4)	18 Feb 2021 15:28:48
	(b) (4)	

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:28:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Adult respiratory distress syndrome'	Whitney West (b) (4)	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '40'	Whitney West (b) (4)	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once daily (QD)'	Whitney West (b) (4)	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '17 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '23 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User entered '1'	System	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User entered '1'	System	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (118)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:41
User entered '804 (804)'	System	18 Feb 2021 15:28:48

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #70. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:25:02
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #70. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' answered with 'information needs listed separately' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:16:42
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #70. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:57:29
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 07:31:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 07:31:08
Data point term sent to Coder	System	18 Feb 2021 15:29:39
User entered 'Prednisone'	Whitney West (b) (4)	18 Feb 2021 15:29:37

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:29:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Adult respiratory distress syndrome'	Whitney West (b) (4)	18 Feb 2021 15:29:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '30'	Whitney West (b) (4)	18 Feb 2021 15:29:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	18 Feb 2021 15:29:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:29:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once daily (QD)'	Whitney West (b) (4)	18 Feb 2021 15:29:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:29:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	18 Feb 2021 15:29:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:29:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:25:06
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:16:58
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:57:37
User entered '24 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 15:29:37

(b)

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 15:29:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:29:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '30 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 15:29:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:29:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User entered '1'	System	18 Feb 2021 15:29:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User entered '1'	System	18 Feb 2021 15:29:37

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (119)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:17:46
User entered '804 (804)'	System	18 Feb 2021 15:29:37

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #71. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:25:34
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #71. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' answered with 'information needs listed separately' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:17:29
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #71. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:58:04
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 07:31:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Feb 2021 07:31:09
Data point term sent to Coder	System	18 Feb 2021 15:30:40
User entered 'Prednisone'	Whitney West (b) (4)	18 Feb 2021 15:30:23

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Adult respiratory distress syndrome'	Whitney West (b) (4)	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20'	Whitney West (b) (4)	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once daily (QD)'	Whitney West (b) (4)	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:25:40
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:17:34
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:58:12
User entered '31 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '07 Feb 2021'	Whitney West (b) (4)	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User entered '1'	System	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User entered '1'	System	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (120)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:07
User entered '804 (804)'	System	18 Feb 2021 15:30:23

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ESMOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 00:57:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 00:57:24
Data point term sent to Coder	System	25 Mar 2021 14:14:24
Coding entries removed.	Whitney West (b) (4)	25 Mar 2021 14:14:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ESMOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 01:02:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 01:02:01
Data point term sent to Coder	System	18 Feb 2021 15:32:41
User entered 'Esmolol'	Whitney West (b) (4)	18 Feb 2021 15:31:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:31:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that ESMOLOL is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:55:19
Query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that ESMOLOL is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'Updated for query.' (Site from DM).	Whitney West (b) (4)	25 Mar 2021 14:14:24
User entered 'EXTRACORPOREAL MEMBRANE OXYGENATION secondary to adult respiratory distress syndrome' reason for change: Per Query Resolution	Whitney West (b) (4)	25 Mar 2021 14:14:13
User opened query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that ESMOLOL is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:26:36
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)	23 Mar 2021 13:26:36
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:17:50

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

[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).	(b) (4), (b) (6)	02 Mar 2021 16:29:27
User entered 'extracorporeal membrane oxygenation'	Whitney West (b) (4)	18 Feb 2021 15:31:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:52:20
User entered '50/200' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 22:18:15
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'pdated' (Site from DM).		19 Mar 2021 22:18:00
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:29:34
User entered '50-200'	Whitney West (b) (4)	18 Feb 2021 15:31:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Other (OTHER)'	Whitney West (b) (4)	18 Feb 2021 15:31:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query ' Per DM CLR: Please review the unit recorded as this reflects the rate of infusion rather than the unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:33:51
Query ' Per DM CLR: Please review the unit recorded as this reflects the rate of infusion rather than the unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:18:20
User opened query ' Per DM CLR: Please review the unit recorded as this reflects the rate of infusion rather than the unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:29:42
User entered 'mcg/kg/min'	Whitney West (b) (4)	18 Feb 2021 15:31:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'other (OTHER)'	Whitney West (b) (4)	18 Feb 2021 15:31:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:51:40
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:18:25
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:29:57
User entered 'Continuous'	Whitney West (b) (4)	18 Feb 2021 15:31:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Whitney West (b) (4)	18 Feb 2021 15:31:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:31:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '06 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 15:31:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 15:31:47

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:31:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '07 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 15:31:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:31:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User entered empty.	System	18 Feb 2021 15:31:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User entered empty.	System	18 Feb 2021 15:31:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (121)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:14
User entered empty.	System	18 Feb 2021 15:31:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:53:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:53:16
Data point term sent to Coder	System	06 Apr 2021 15:43:39
Coding entries removed.	Whitney West (b) (4) (b) (4)	06 Apr 2021 15:42:47
User closed query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #94. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:26:54
Query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #94. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' answered with 'information needs listed separately' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:18:47
User opened query 'Per DM CLR: Please review the dates of this medication as it overlap with the dates of ConMed #94. Please reconcile dates and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify. Please also note that multiple conditions can be recorded as Indication for a medication.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:32:45

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 08:13:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 08:13:48
Data point term sent to Coder	System	18 Feb 2021 15:34:45
User entered 'Furosemide'	Whitney West (b) (4) (b) (4)	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that FUROSEMIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).		07 Apr 2021 11:39:16
Query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that FUROSEMIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'Increased.' (Site from DM).	Whitney West (b) (4)	06 Apr 2021 15:42:57
User entered 'EXTRACORPOREAL MEMBRANE OXYGENATION secondary to adult respiratory distress syndrome, COVID-19' reason for change: Per Query Resolution	Whitney West (b) (4)	06 Apr 2021 15:42:47
User opened query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that FUROSEMIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:27:25
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:27:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:18:53
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:33:02
User entered 'Extracorporeal membrane oxygenation, Whitney West Covid-19'	(b) (4)	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20'	Whitney West (b) (4)	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'as needed (PRN)'	Whitney West (b) (4)	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '18 Nov 2020'	Whitney West (b) (4)	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User entered empty.	System	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User entered empty.	System	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (122)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:12
User entered empty.	System	18 Feb 2021 15:33:44

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, PRODUCT: ACETAZOLAMIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 14:17:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 14:17:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, PRODUCT: ACETAZOLAMIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 14:01:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Mar 2021 14:01:28
Data point term sent to Coder	System	25 Mar 2021 14:00:56
Coding entries removed.	Whitney West (b) (4)	25 Mar 2021 14:00:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, PRODUCT: ACETAZOLAMIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 15:43:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 15:43:52
Data point term sent to Coder	System	18 Feb 2021 15:42:52
User entered 'Acetazolamide'	Whitney West (b) (4)	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that ACETAZOLAMIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:55:07
Query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that ACETAZOLAMIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' answered with 'Updated to satisfy query.' (Site from DM).	Whitney West (b) (4)	25 Mar 2021 14:00:18
User entered 'EXTRACORPOREAL MEMBRANE OXYGENATION secondary to adult respiratory distress syndrome' reason for change: Per Query Resolution	Whitney West (b) (4)	25 Mar 2021 14:00:04
User opened query 'Per CDM: Response does not satisfy query. Please provide the indication to reflect the underlying medical condition that ACETAZOLAMIDE is being used to treat rather than the drug class or mechanism of action. Please reconcile with AE or Med History eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:28:20
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:28:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:19:07
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:10:52
User entered 'Extracorporeal membrane oxygenation' Whitney West	(b) (4)	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '250'	Whitney West (b) (4)	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'twice daily (BID)'	Whitney West (b) (4)	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '23 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 15:42:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 15:42:42
User entered 'No (N)' reason for change: Data Entry Error	Whitney West (b) (4)	18 Feb 2021 15:42:42
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 15:42:26
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '23 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User entered '2'	System	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User entered '1'	System	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (123)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:16
User entered '804 (804)'	System	18 Feb 2021 15:42:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 21:20:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 21:20:56
Data point term sent to Coder	System	18 Feb 2021 15:48:02
User entered 'Cefazolin'	Whitney West (b) (4)	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Yes (Y)'	Whitney West (b) (4)	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Bronchoscopy prophylaxis'	Whitney West (b) (4)	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'l'	Whitney West (b) (4)	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'g (g)'	Whitney West (b) (4)	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'three times daily (TID)'	Whitney West (b) (4)	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '22 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '23 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User entered '3'	System	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User entered '1'	System	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (124)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:18:36
User entered '804 (804)'	System	18 Feb 2021 15:47:24

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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)	04 Mar 2021 11:29:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Mar 2021 11:29:58
Data point term sent to Coder	System	18 Feb 2021 15:49:03
User entered 'Influenza Quad-QIV'	Whitney West (b) (4)	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Yes (Y)'	Whitney West (b) (4)	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Influenza prophylaxis'	Whitney West (b) (4)	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0.5'	Whitney West (b) (4)	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mL (mL)'	Whitney West (b) (4)	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once (ONCE)'	Whitney West (b) (4)	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intramuscular (INTRAMUSCULAR)'	Whitney West (b) (4)	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '28 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '28 Jan 2021'	Whitney West (b) (4)	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User entered empty.	System	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User entered empty.	System	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (125)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:42
User entered empty.	System	18 Feb 2021 15:48:18

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 17:43:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 17:43:27
Data point term sent to Coder	System	18 Feb 2021 16:06:35
User entered 'Vancomycin'	Whitney West (b) (4) (b) (4)	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Multifocal pneumonia'	Whitney West (b) (4)	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '1750'	Whitney West (b) (4)	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'twice daily (BID)'	Whitney West (b) (4)	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '14 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '14 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User entered '2'	System	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User entered '1'	System	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (126)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:19:50
User entered '804 (804)'	System	18 Feb 2021 16:06:13

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
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: AMPICILLIN;SULBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 08:43:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 08:43:37
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: AMPICILLIN SODIUM;SULBACTAM SODIUM, PRODUCTSYNONYM: AMPICILLIN/SULBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 16:09:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 16:09:59
Data point term sent to Coder	System	18 Feb 2021 16:08:40
User entered 'Ampicillin/Sulbactam'	Whitney West (b) (4)	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Yes (Y)'	Whitney West (b) (4)	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Extracorporeal membrane oxygenation circuit exchange prophylaxis'	Whitney West (b) (4)	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '3'	Whitney West (b) (4)	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'g (g)'	Whitney West (b) (4)	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'four times daily (QID)'	Whitney West (b) (4)	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '28 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '29 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User entered '4'	System	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User entered '1'	System	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (127)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:13
User entered '804 (804)'	System	18 Feb 2021 16:07:56

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: DERMATOLOGICALS, ATC: EMOLLIENTS AND PROTECTIVES, ATC: EMOLLIENTS AND PROTECTIVES, ATC: SOFT PARAFFIN AND FAT PRODUCTS, PRODUCT: PETROLATUM, PRODUCTSYNONYM: ALOE VESTA PROTECT - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 07:08:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 07:08:40
Data point term sent to Coder	System	06 Apr 2021 15:56:59
Coding entries removed.	Whitney West (b) (4) (b) (4)	06 Apr 2021 15:56:02
User coded data point as ATC: DERMATOLOGICALS, ATC: EMOLLIENTS AND PROTECTIVES, ATC: EMOLLIENTS AND PROTECTIVES, ATC: SOFT PARAFFIN AND FAT PRODUCTS, PRODUCT: PETROLATUM, PRODUCTSYNONYM: ALOE VESTA PROTECT - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 18:06:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 18:06:55
Data point term sent to Coder	System	18 Feb 2021 16:12:51
User entered 'Aloe vesta protectant ointment #3'	Whitney West (b) (4) (b) (4)	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User closed query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:44:35
Query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' answered with 'Updated order. ' (Site from DM).	Whitney West (b) (4)	06 Apr 2021 15:56:18
User entered 'PRESSURE SORES, NOSE, BILATERAL CHEEKS, COCCYX' reason for change: Data Entry Error	Whitney West (b) (4)	06 Apr 2021 15:56:02
User opened query 'Per CDM: Please note, there is no AE/MH that matches this Con Med indication during this timeframe? Please review and add an entry and applicable details to the relevant eCRF as appropriate or, provide record number this indication pertains to. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:30:27
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:30:27
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'per subject data correct' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 22:19:24

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

[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. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:11:46
User entered 'Pressure sores, bilateral cheeks, coccyx, Whitney West nose'	(b) (4)	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'I'	Whitney West (b) (4)	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Other (OTHER)'	Whitney West (b) (4)	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'application'	Whitney West (b) (4)	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'twice daily (BID)'	Whitney West (b) (4)	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Topical (TOPICAL)'	Whitney West (b) (4)	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '24 Dec 2020'	Whitney West (b) (4)	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '10 Feb 2021'	Whitney West (b) (4)	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User entered '2'	System	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User entered '1'	System	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (128)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:18
User entered '804 (804)'	System	18 Feb 2021 16:12:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 16:16:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 16:16:53
Data point term sent to Coder	System	18 Feb 2021 16:16:00
User entered 'Cefepime'	Whitney West (b) (4)	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Multifocal pneumonia'	Whitney West (b) (4)	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'l'	Whitney West (b) (4)	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'g (g)'	Whitney West (b) (4)	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'four times daily (QID)'	Whitney West (b) (4)	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intravenous (INTRAVENOUS)'	Whitney West (b) (4)	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '25 Nov 2020'	Whitney West (b) (4)	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '27 Nov 2020'	Whitney West (b) (4)	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User entered '4'	System	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User entered '1'	System	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (129)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:22
User entered '804 (804)'	System	18 Feb 2021 16:15:09

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:10:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:10:45
Data point term sent to Coder	System	24 Mar 2021 22:31:09
User entered 'Gabapentin'	Whitney West (b) (4)	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Left lower extremity paresthesia'	Whitney West (b) (4)	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '300'	Whitney West (b) (4)	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'three times daily (TID)'	Whitney West (b) (4)	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '06 Feb 2021'	Whitney West (b) (4)	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Yes (Y)'	Whitney West (b) (4)	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '3'	System	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '1'	System	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (130)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '804 (804)'	System	24 Mar 2021 22:30:57

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:10:12
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 Mar 2021 14:10:12
Data point term sent to Coder	System	24 Mar 2021 22:33:11
User entered 'Gabapentin'	Whitney West (b) (4) (b) (4)	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Left lower leg parasthesia'	Whitney West (b) (4)	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '100'	Whitney West (b) (4)	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'three times daily (TID)'	Whitney West (b) (4)	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '01 Feb 2021'	Whitney West (b) (4)	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '05 Feb 2021'	Whitney West (b) (4)	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User entered '3'	System	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User entered '1'	System	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (131)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:20:56
User entered '804 (804)'	System	24 Mar 2021 22:32:20

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 15:34:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 15:34:22
Data point term sent to Coder	System	06 Apr 2021 15:33:14
User entered 'Potassium Chloride'	Whitney West (b) (4)	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Hypokalemia'	Whitney West (b) (4)	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20'	Whitney West (b) (4)	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Other (OTHER)'	Whitney West (b) (4)	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mEq'	Whitney West (b) (4)	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once daily (QD)'	Whitney West (b) (4)	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '09 Feb 2021'	Whitney West (b) (4)	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '11 Feb 2021'	Whitney West (b) (4)	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User entered '1'	System	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User entered '1'	System	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (132)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:00
User entered '804 (804)'	System	06 Apr 2021 15:32:27

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:53:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:53:15
Data point term sent to Coder	System	06 Apr 2021 16:38:58
User entered 'Furosemide'	Whitney West (b) (4) (b) (4)	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Edema, bilateral lower extremities'	Whitney West (b) (4)	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '20'	Whitney West (b) (4)	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mg (mg)'	Whitney West (b) (4)	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once daily (QD)'	Whitney West (b) (4)	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Oral (ORAL)'	Whitney West (b) (4)	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.	Whitney West (b) (4)	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '03 Feb 2021'	Whitney West (b) (4)	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'	Whitney West (b) (4)	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '08 Feb 2021'	Whitney West (b) (4)	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'	Whitney West (b) (4)	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User entered '1'	System	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User entered '1'	System	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (133)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:21:04
User entered '804 (804)'	System	06 Apr 2021 16:38:26

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per MM: please provide name of vaccine. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 07:53:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 19:32:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 19:32:25
Query 'Per MM: please provide name of vaccine. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 18:52:06
Data point term sent to Coder	System	28 Apr 2021 18:51:58
DataPoint Un-verified.	(b) (4), (b) (6)	28 Apr 2021 18:51:48
Coding entries removed.		28 Apr 2021 18:51:48
User entered 'COVID VACCINE (Pfizer)' reason for change: Data Entry Error		28 Apr 2021 18:51:48
User opened query 'Per MM: please provide name of vaccine. ' (Site from DM).		26 Apr 2021 01:02:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 03:52:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 03:52:40
Data point term sent to Coder	System	08 Apr 2021 22:32:05
User entered 'Covid Vaccine'	(b) (4), (b) (6)	08 Apr 2021 22:31:58

PRODUCTION RELEASE (v12.003
EAB) (1725)

6408 of 6887

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Yes (Y)'		08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Covid prevention'		08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '.5'		08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'mL (mL)'		08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.		08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'once (ONCE)'		08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.		08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'Intramuscular (INTRAMUSCULAR)'		08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered empty.		08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'un UNK 2021'		08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered '0'		08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'		08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'un UNK 2021'		08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:12:50
User entered 'No (N)'		08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (134)

Generated On: 09 Jun 2021 16:18:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered empty.	System	08 Apr 2021 22:31:58

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:18:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:39:01
User entered 'Yes (Y)' reason for change: Data Entry Error		17 Nov 2020 19:51:27
User entered 'No (N)'	Ashley Bell (b) (4)	01 Aug 2020 16:47:33

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered '17 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 18:40:48

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered 'Midline placement, single lumen'	Whitney West (b) (4)	08 Dec 2020 18:40:48

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	08 Dec 2020 18:40:48

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered empty.	Whitney West (b) (4)	08 Dec 2020 18:40:48

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered '28 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 20:36:26

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered 'Arterial Line, right arm'	Whitney West (b) (4)	08 Dec 2020 20:36:26

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	08 Dec 2020 20:36:26

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:18
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:36:26

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered '28 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 20:36:58

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered 'OROGASTRIC TUBE INSERTION' reason for change: Data Entry Error	Whitney West (b) (4)	08 Dec 2020 21:16:26
User entered 'Nasogastric tube insertion'	Whitney West (b) (4)	08 Dec 2020 20:36:58

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	08 Dec 2020 20:36:58

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:36:58

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered '28 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 20:37:44

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered 'Foley Catheter Placed'	Whitney West (b) (4)	08 Dec 2020 20:37:44

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	08 Dec 2020 20:37:44

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:23:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:37:44

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered '28 Nov 2020'	Whitney West (b) (4)	08 Dec 2020 20:37:59

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered 'Intubated'	Whitney West (b) (4)	08 Dec 2020 20:37:59

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	08 Dec 2020 20:37:59

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:24:03
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered empty.	Whitney West (b) (4)	08 Dec 2020 20:37:59

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered '02 Dec 2020'	Whitney West (b) (4)	11 Dec 2020 00:20:16

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered 'Femoral-femoral veno-venous extracorporeal membrane machine catheterization.'	Whitney West (b) (4)	11 Dec 2020 00:20:16

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	11 Dec 2020 00:20:16

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:06
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered empty.	Whitney West (b) (4)	11 Dec 2020 00:20:16

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered '16 Nov 2020'	Whitney West (b) (4)	11 Dec 2020 00:42:44

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered 'Bipap initiated'	Whitney West (b) (4)	11 Dec 2020 00:42:44

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	11 Dec 2020 00:42:44

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 17:21:24
User entered empty.	Whitney West (b) (4)	11 Dec 2020 00:42:44

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered '18 Jan 2021' reason for change: Data Entry Error	Whitney West (b) (4)	17 Feb 2021 15:56:59
User entered '20 Jan 2021'	Whitney West (b) (4)	05 Feb 2021 21:39:33
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	05 Feb 2021 21:37:09
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	11 Dec 2020 00:41:28

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Bronchoscopy'	Whitney West (b) (4)	05 Feb 2021 21:39:33
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	05 Feb 2021 21:37:09
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	11 Dec 2020 00:41:28

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	05 Feb 2021 21:39:33
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	05 Feb 2021 21:37:09
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	11 Dec 2020 00:41:28

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:22:54
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:39:33
DataPoint activated with code reason code Data required.	Whitney West (b) (4)	05 Feb 2021 21:37:09
DataPoint inactivated with code reason code Data not required.	Whitney West (b) (4)	11 Dec 2020 00:41:28

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered '10 Dec 2020' reason for change: Data Entry Error	Whitney West (b) (4)	05 Feb 2021 22:31:01
User entered '11 Dec 2020'	Whitney West (b) (4)	30 Dec 2020 17:21:04

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Tracheotomy/Tracheostomy'	Whitney West (b) (4)	30 Dec 2020 17:21:04

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	30 Dec 2020 17:21:04

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:22
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered empty.	Whitney West (b) (4)	30 Dec 2020 17:21:04

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered '25 Jan 2021'	Whitney West (b) (4)	05 Feb 2021 21:52:06

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Trachea decannulation'	Whitney West (b) (4)	05 Feb 2021 21:52:06

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	05 Feb 2021 21:52:06

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:33
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered empty.	Whitney West (b) (4)	05 Feb 2021 21:52:06

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered '06 Jan 2021'	Whitney West (b) (4)	05 Feb 2021 22:06:27

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Inferior vena cava filter placement'	Whitney West (b) (4)	05 Feb 2021 22:06:27

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	05 Feb 2021 22:06:27

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:44
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered empty.	Whitney West (b) (4)	05 Feb 2021 22:06:27

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered '14 Dec 2020'	Whitney West (b) (4)	06 Feb 2021 23:48:52

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Bronchoscopy'	Whitney West (b) (4)	06 Feb 2021 23:48:52

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	06 Feb 2021 23:48:52

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered empty.	Whitney West (b) (4)	06 Feb 2021 23:48:52

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered '21 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 16:35:01

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Rhino Rocket procedure'	Whitney West (b) (4)	17 Feb 2021 16:35:01

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	17 Feb 2021 16:35:01

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:36
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:35:01

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	17 Feb 2021 16:35:56
User entered '23 Dec 2020' reason for change: Data Entry Error	Whitney West (b) (4)	17 Feb 2021 16:35:56
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	17 Feb 2021 16:35:39
User entered '23 Dec 2021'	Whitney West (b) (4)	17 Feb 2021 16:35:39

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Bronchoscopy'	Whitney West (b) (4)	17 Feb 2021 16:35:39

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	17 Feb 2021 16:35:39

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:56
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:35:39

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered '31 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 16:36:37

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Bronchoscopy'	Whitney West (b) (4)	17 Feb 2021 16:36:37

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	17 Feb 2021 16:36:37

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:25:59
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:36:37

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered '14 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 16:37:32

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Extracorporeal membrane oxygenation circuit exchange'	Whitney West (b) (4)	17 Feb 2021 16:37:32

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	17 Feb 2021 16:37:32

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:17
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:37:32

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered '17 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 16:38:07

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Extracorporeal membrane oxygenation circuit exchange'	Whitney West (b) (4)	17 Feb 2021 16:38:07

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	17 Feb 2021 16:38:07

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:23
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:38:07

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered '26 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 16:38:35

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Extracorporeal membrane oxygenation circuit exchange'	Whitney West (b) (4)	17 Feb 2021 16:38:35

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	17 Feb 2021 16:38:35

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:26
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:38:35

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered '01 Jan 2021'	Whitney West (b) (4)	17 Feb 2021 16:41:33

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Femoral-femoral ven-venous extracorporeal membrane machine de-cannulation'	Whitney West (b) (4)	17 Feb 2021 16:41:33

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	17 Feb 2021 16:41:33

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:50
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:41:33

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered '04 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 16:43:35

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Bronchoscopy'	Whitney West (b) (4)	17 Feb 2021 16:43:35

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Whitney West (b) (4)	17 Feb 2021 16:44:05
User entered 'Medical History (MH)'	Whitney West (b) (4)	17 Feb 2021 16:43:35

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:05
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:43:35

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (32)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered '08 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 16:43:54

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (32)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Bronchoscopy'	Whitney West (b) (4)	17 Feb 2021 16:43:54

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (32)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	17 Feb 2021 16:43:54

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (32)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:19
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:43:54

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (33)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered '13 Dec 2020'	Whitney West (b) (4)	17 Feb 2021 16:44:55

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (33)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Bronchoscopy'	Whitney West (b) (4)	17 Feb 2021 16:44:55

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (33)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	17 Feb 2021 16:44:55

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (33)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:27:09
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:21:24
User entered empty.	Whitney West (b) (4)	17 Feb 2021 16:44:55

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (34)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered '28 Nov 2020'	Whitney West (b) (4)	14 Apr 2021 14:18:57

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (34)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Tube feeding'	Whitney West (b) (4)	14 Apr 2021 14:18:57

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (34)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	14 Apr 2021 14:18:57

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (34)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:55
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered empty.	Whitney West (b) (4)	14 Apr 2021 14:18:57

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (35)

Generated On: 09 Jun 2021 16:18:59

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered '14 Dec 2020'	Whitney West (b) (4)	14 Apr 2021 14:19:27

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (35)

Generated On: 09 Jun 2021 16:18:59

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Enema, Smog'	Whitney West (b) (4)	14 Apr 2021 14:19:27

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (35)

Generated On: 09 Jun 2021 16:18:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered 'Adverse Event (AE)'	Whitney West (b) (4)	14 Apr 2021 14:19:27

US3272026

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (35)

Generated On: 09 Jun 2021 16:18:59

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:28:31
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User entered empty.	Whitney West (b) (4)	14 Apr 2021 14:19:27

US3272026

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:22:00
User entered '25 Mar 2021'	Ashley Bell (b) (4)	31 Mar 2021 19:49:05

US3272026

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:18:59

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
User closed query 'Per CDM: please clarify if the subject received a non-study COVID vaccine PRIOR to withdrawal from the study. If yes, please agree to select protocol deviation. If no, please select the appropriate reason for discontinuation.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 12:34:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:22:00
Query 'Per CDM: please clarify if the subject received a non-study COVID vaccine PRIOR to withdrawal from the study. If yes, please agree to select protocol deviation. If no, please select the appropriate reason for discontinuation.' answered with 'Protocol deviation noted' (Site from DM).		09 Apr 2021 19:52:11
User opened query 'Per CDM: please clarify if the subject received a non-study COVID vaccine PRIOR to withdrawal from the study. If yes, please agree to select protocol deviation. If no, please select the appropriate reason for discontinuation.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:35:03
User closed query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' (Site from DM).		09 Apr 2021 09:42:19
Query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation. answered with 'updated' (Site from DM).		08 Apr 2021 21:20:26
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: Data Entry Error		08 Apr 2021 21:20:09
User opened query 'Per CDM: per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 10:44:06
User entered 'Other (OTHER)'	Ashley Bell (b) (4)	31 Mar 2021 19:49:05

US3272026

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:18:59

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)	30 Apr 2021 19:07:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:22:00
User entered 'Subject received non-study vaccine outside of study. per sponsor subject is to be discontinued.'	Ashley Bell (b) (4)	31 Mar 2021 19:49:05

US3272026

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:18:59

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:22:00
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:49:05

US3272026

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:18:59

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:22:00
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:49:05

US3272026

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:18:59

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:22:00
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:49:05

US3272026

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:18:59

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:07:10
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:22:00
User entered empty.	Ashley Bell (b) (4)	31 Mar 2021 19:49:05

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	1 Dec 2020 20:15:24
Un-reviewed for Safety.		1 Dec 2020 14:24:55
DataPoint Verified.		0 Nov 2020 15:41:05
Reviewed for Safety.		7 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 14:24:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
User entered '17/Nov/2020 14:11'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'I'		17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
User entered '18/Nov/2020 10:47'	System	18 Nov 2020 15:47:46

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'I'		18 Nov 2020 15:47:46

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 14:24:55
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 20:01:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 19:29:17
User entered '20/Nov/2020 15:02'	System	20 Nov 2020 20:02:04

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		30 Nov 2020 17:30:20
DataPoint Verified.		21 Nov 2020 19:29:17
User entered 'I'		20 Nov 2020 20:02:04

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:11:39
User entered '30/Nov/2020 17:30'	System	30 Nov 2020 17:30:32

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:11:39
Reviewed for Safety.		11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		06 Dec 2020 15:55:16
User entered 'I'		30 Nov 2020 17:30:32

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:11:39
User entered '06/Dec/2020 15:55'	System	06 Dec 2020 15:55:28

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:11:39
Reviewed for Safety.		11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		11 Dec 2020 14:13:44
User entered 'I'		06 Dec 2020 15:55:28

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:11:39
Reviewed for Safety.		11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		11 Dec 2020 14:14:29
User entered '0'		11 Dec 2020 14:13:56

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'		17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 14:24:55
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 20:01:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 14:24:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:11:39
User entered '11/Dec/2020 09:25'	System	11 Dec 2020 14:25:21

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:18:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:11:39
Reviewed for Safety.		11 Dec 2020 14:25:30
User entered 'I'		11 Dec 2020 14:25:21

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:11:39
User entered '11/Dec/2020 20:25'	System	11 Dec 2020 20:25:02

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:18:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:11:39
Reviewed for Safety.		15 Dec 2020 17:20:08
User entered 'I'		11 Dec 2020 20:25:02

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 14:24:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:11:39
User entered '15/Dec/2020 09:20'	System	15 Dec 2020 17:20:28

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:18:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:11:39
Reviewed for Safety.		16 Dec 2020 14:07:00
User entered 'I'		15 Dec 2020 17:20:28

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 14:24:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	17 Dec 2020 19:11:39
User entered '16/Dec/2020 09:09'	System	16 Dec 2020 14:09:09

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 16:18:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 16:48:50
DataPoint Verified.		17 Dec 2020 19:11:39
User entered 'I'		16 Dec 2020 14:09:09

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 14:24:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 16:18:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:44:07
Reviewed for Safety.		21 Dec 2020 16:49:21
User entered '0'		21 Dec 2020 16:49:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:44:07
User entered '21/Dec/2020 11:49'	System	21 Dec 2020 16:49:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 16:18:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:44:07
Reviewed for Safety.		21 Dec 2020 16:49:21
User entered 'I'		21 Dec 2020 16:49:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 14:24:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 14:24:55
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 20:01:47
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:41:01
User entered '22/Dec/2020 21:44'	System	22 Dec 2020 21:44:53

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 16:18:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:41:02
Reviewed for Safety.		29 Jan 2021 18:48:58
User entered 'I'		22 Dec 2020 21:44:53

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 14:24:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (14)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:41:12
User entered '29/Jan/2021 13:49'	System	29 Jan 2021 18:49:12

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (14)

Generated On: 09 Jun 2021 16:18:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:41:16
Reviewed for Safety.		05 Feb 2021 14:22:01
User entered 'I'		29 Jan 2021 18:49:12

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (15)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:41:23
User entered '05/Feb/2021 14:22'	System	05 Feb 2021 14:22:21

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (15)

Generated On: 09 Jun 2021 16:18:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:41:25
Reviewed for Safety.		08 Feb 2021 12:58:43
User entered 'I'		05 Feb 2021 14:22:21

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 14:24:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 14:24:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (16)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:41:33
User entered '08/Feb/2021 12:59'	System	08 Feb 2021 12:59:07

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (16)

Generated On: 09 Jun 2021 16:18:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:41:35
Reviewed for Safety.		18 Feb 2021 14:34:17
Un-reviewed for Safety.		08 Feb 2021 12:59:07
User entered '1' reason for change: Data Entry Error		08 Feb 2021 12:59:07
Reviewed for Safety.		08 Feb 2021 12:58:43
User entered '0'		05 Feb 2021 14:22:21

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (17)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (17)

Generated On: 09 Jun 2021 16:18:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:43:30
Reviewed for Safety.		18 Feb 2021 14:34:17
User entered '0'		08 Feb 2021 12:59:07

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 14:24:55
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 15:41:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'		17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (18)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:43:42
User entered '16/Feb/2021 12:58'	System	16 Feb 2021 17:58:55

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (18)

Generated On: 09 Jun 2021 16:18:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:43:44
Reviewed for Safety.		18 Feb 2021 14:34:17
User entered 'I'		16 Feb 2021 17:58:55

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'USA-US070-2020-MRNA-1273-P301000019'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Yes (Y)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
Un-reviewed for Safety.	System	17 Nov 2020 19:49:22
User entered 'Yes (Y)'	System	17 Nov 2020 19:49:22
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'No (N)'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Adam'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Brosz'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '2444 W. Faidley Ave'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'Grand Island'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered 'NE'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
DataPoint Verified.		20 Nov 2020 15:41:05
Reviewed for Safety.		17 Nov 2020 19:11:10
User entered '68803'	System	17 Nov 2020 19:10:49

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 20:15:24
Un-reviewed for Safety.		11 Dec 2020 14:24:55
Reviewed for Safety.		20 Nov 2020 20:01:47
DataPoint Verified.		20 Nov 2020 15:41:05
User entered 'US'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form

Generated On: 09 Jun 2021 16:18:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User entered '16'	System	18 Feb 2021 14:34:12
User entered '15'	System	16 Feb 2021 17:58:55
User entered '14'	System	08 Feb 2021 12:59:07
User entered '13'	System	05 Feb 2021 14:22:21
User entered '12'	System	29 Jan 2021 18:49:12
User entered '11'	System	22 Dec 2020 21:44:53
User entered '10'	System	21 Dec 2020 16:49:17
User entered '9'	System	16 Dec 2020 14:09:09
User entered '8'	System	15 Dec 2020 17:20:28
User entered '7'	System	11 Dec 2020 20:25:02
User entered '6'	System	11 Dec 2020 14:25:21
User entered '5'	System	06 Dec 2020 15:55:28
User entered '4'	System	30 Nov 2020 17:30:32
User entered '3'	System	20 Nov 2020 20:02:04
User entered '2'	System	18 Nov 2020 15:47:46
User entered '1'	System	17 Nov 2020 19:11:17

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (19)

Generated On: 09 Jun 2021 16:18:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:43:56
User entered '18/Feb/2021 09:34'	System	18 Feb 2021 14:34:12

US3272026

Folder: SAE USA-US070-2020-MRNA-1273-P301000019

Form: Safety Report Form (19)

Generated On: 09 Jun 2021 16:18:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:50:11
User signature succeeded.	Adam Brosz (b) (4)	29 Apr 2021 16:56:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 14:44:01
Reviewed for Safety.		18 Feb 2021 14:34:17
User entered 'I'		18 Feb 2021 14:34:12