

US3622169 (Prod: University of Miami)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:14:19

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US3622169

Form: Participant Creation

Data signed: (b) (4) 13 Sep 2020 16:37:12

Generated On: 10 Jun 2021 09:14:19

[Participant ID](#)

US3622169

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

US3622169

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Sep 2020 16:37:12

Generated On: 10 Jun 2021 09:14:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	09 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3622169

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Sep 2020 16:37:12

Generated On: 10 Jun 2021 09:14:19

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

US3622169

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Sep 2020 16:37:12

Generated On: 10 Jun 2021 09:14:19

Date of Informed Consent (dd MMM yyyy)	9 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Sep 2020 16:37:12

Generated On: 10 Jun 2021 09:14:19

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Sep 2020 16:37:12

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Sep 2020 16:37:12

Generated On: 10 Jun 2021 09:14:19

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Sep 2020 16:37:12

Generated On: 10 Jun 2021 09:14:19

Condition	DIABETES
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Sep 2020 16:37:12

Generated On: 10 Jun 2021 09:14:19

Condition	SEVERE OBESITY (BMI 49.6)
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Sep 2020 16:37:12

Generated On: 10 Jun 2021 09:14:19

Condition	DYSYPNEA
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3622169

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Sep 2020 16:37:12

Generated On: 10 Jun 2021 09:14:19

Condition	FLUID RETENTION
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Sep 2020 16:37:12

Generated On: 10 Jun 2021 09:14:19

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	9 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:22 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 09:22
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	317 lb
BMI (<i>xxx.x</i>)	49.75303 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Sep 2020 16:37:12

Generated On: 10 Jun 2021 09:14:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Sep 2020 16:37:12

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

DISABLED, SOCIALLY ACTIVE

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) 13 Sep 2020 16:37:12

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Sep 2020 16:37:13

Generated On: 10 Jun 2021 09:14:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	9 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 08 Oct 2020 13:42:32

Generated On: 10 Jun 2021 09:14:19

What was the date of randomization? (dd MMM yyyy) 09 SEP 2020

What was the participant's randomization number? 146057

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Sep 2020 16:37:13

Generated On: 10 Jun 2021 09:14:19

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) 13 Sep 2020 16:37:13

Generated On: 10 Jun 2021 09:14:19

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	09:22 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 09:22
Temperature (xxx.x)	98.6 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Sep 2020 16:37:13

Generated On: 10 Jun 2021 09:14:19

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	9 SEP 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 11:50
Temperature (xxx.x)	98.5 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	24 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Sep 2020 16:37:13

Generated On: 10 Jun 2021 09:14:19

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Sep 2020 16:37:12

Generated On: 10 Jun 2021 09:14:19

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) 9 SEP 2020

What was the treatment time? (00:00-23:59) 11:12 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 11:12

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) 13 Sep 2020 16:37:13

Generated On: 10 Jun 2021 09:14:19

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	9 SEP 2020
Collection time (00:00-23:59)	09:30 (24 HR)
Collection date and time (derived)	9 SEP 2020 09:30

US3622169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Sep 2020 16:37:12

Generated On: 10 Jun 2021 09:14:19

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:35	9 SEP 2020 09:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Sep 2020 16:37:12

Generated On: 10 Jun 2021 09:14:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

98.5 °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 11:56

PC Open Date & Time 09 SEP 2020 11:32

PC Close Date & Time 09 SEP 2020 14:02

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	09 SEP 2020 19:10
PC Open Date & Time	09 SEP 2020 14:57
PC Close Date & Time	10 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

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

98.8 °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

10 SEP 2020 19:01

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °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

11 SEP 2020 18:58

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

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

98.3 °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

12 SEP 2020 19:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

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

98.2 °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

13 SEP 2020 19:06

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

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

98.2 °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

14 SEP 2020 19:02

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

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

15 SEP 2020 18:50

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

09 SEP 2020 11:57

PC Open Date & Time

09 SEP 2020 11:32

PC Close Date & Time

09 SEP 2020 14:02

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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

09 SEP 2020 19:10

PC Open Date & Time

09 SEP 2020 14:57

PC Close Date & Time

10 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

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

10 SEP 2020 19:01

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

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

11 SEP 2020 18:59

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

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

12 SEP 2020 19:02

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

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

13 SEP 2020 19:07

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

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

14 SEP 2020 19:02

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

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

15 SEP 2020 18:50

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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 ☐

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 11:58
PC Open Date & Time	09 SEP 2020 11:32
PC Close Date & Time	09 SEP 2020 14:02

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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 ☐

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 19:11
PC Open Date & Time	09 SEP 2020 14:57
PC Close Date & Time	10 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

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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US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

Yes ☐	
PC Time stamp	10 SEP 2020 19:02
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

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)

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

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

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

Yes ☐	
PC Time stamp	12 SEP 2020 19:03
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

Yes ☐	
PC Time stamp	13 SEP 2020 19:07
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

Yes ☐	
PC Time stamp	14 SEP 2020 19:02
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

Yes ☐	
PC Time stamp	15 SEP 2020 18:51
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3622169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Sep 2020 13:04:46

Generated On: 10 Jun 2021 09:14:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622169

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Sep 2020 13:04:46

Generated On: 10 Jun 2021 09:14:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 13:42:32

Generated On: 10 Jun 2021 09:14:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622169

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 13:42:32

Generated On: 10 Jun 2021 09:14:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 08 Oct 2020 13:42:32

Generated On: 10 Jun 2021 09:14:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622169

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 13:42:32

Generated On: 10 Jun 2021 09:14:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Oct 2020 13:42:32

Generated On: 10 Jun 2021 09:14:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Oct 2020 13:42:32

Generated On: 10 Jun 2021 09:14:19

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	7 OCT 2020
Time of assessment (00:00-23:59)	07:35 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 07:35
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Oct 2020 13:42:32

Generated On: 10 Jun 2021 09:14:19

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	7 OCT 2020
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 09:20
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3622169

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Oct 2020 13:42:32

Generated On: 10 Jun 2021 09:14:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

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

US3622169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 08 Oct 2020 13:42:32

Generated On: 10 Jun 2021 09:14:19

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) 7 OCT 2020

What was the treatment time? (00:00-23:59) 08:47 (24 HR)

Treatment Date and Time (derived) 7 OCT 2020 08:47

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

What was the frequency of the study treatment dosing? ONCE

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

US3622169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Oct 2020 13:42:32

Generated On: 10 Jun 2021 09:14:19

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	7 OCT 2020
Collection time (00:00-23:59)	07:40 (24 HR)
Collection date and time (derived)	7 OCT 2020 07:40

US3622169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 08 Oct 2020 13:42:32

Generated On: 10 Jun 2021 09:14:19

Collection date (dd MMM yyyy)			7 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:47	7 OCT 2020 07:47
Nasopharyngeal Swab 2	No		

US3622169

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 08 Oct 2020 13:42:32

Generated On: 10 Jun 2021 09:14:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 09:22

PC Open Date & Time

07 OCT 2020 09:07

PC Close Date & Time

07 OCT 2020 11:37

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	07 OCT 2020 18:58
PC Open Date & Time	07 OCT 2020 12:32
PC Close Date & Time	08 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 22:05

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

09 OCT 2020 18:25

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

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

98.5 °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

10 OCT 2020 16:27

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

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

98.2 °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 12 OCT 2020 17:01

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

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

98.5 °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

13 OCT 2020 15:17

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 09:23

PC Open Date & Time

07 OCT 2020 09:07

PC Close Date & Time

07 OCT 2020 11:37

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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

07 OCT 2020 18:58

PC Open Date & Time

07 OCT 2020 12:32

PC Close Date & Time

08 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

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

08 OCT 2020 22:05

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

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

09 OCT 2020 18:25

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

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

10 OCT 2020 16:27

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

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

12 OCT 2020 17:01

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

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

13 OCT 2020 15:17

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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 ☐

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 09:23
PC Open Date & Time	07 OCT 2020 09:07
PC Close Date & Time	07 OCT 2020 11:37

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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 ☐

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 18:59
PC Open Date & Time	07 OCT 2020 12:32
PC Close Date & Time	08 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

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)

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

Yes ☐	
PC Time stamp	08 OCT 2020 22:05
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

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)

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

Yes ☐	
PC Time stamp	09 OCT 2020 18:26
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

Yes ☐	
PC Time stamp	10 OCT 2020 16:28
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

Yes ☐

PC Time stamp

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

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)

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

Yes ☐	
PC Time stamp	12 OCT 2020 17:02
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

Yes ☐	
PC Time stamp	13 OCT 2020 15:17
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3622169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Oct 2020 20:03:59

Generated On: 10 Jun 2021 09:14:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622169

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Oct 2020 20:03:59

Generated On: 10 Jun 2021 09:14:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 24 Oct 2020 14:58:40

Generated On: 10 Jun 2021 09:14:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622169

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 24 Oct 2020 14:58:40

Generated On: 10 Jun 2021 09:14:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 10 Nov 2020 16:31:17

Generated On: 10 Jun 2021 09:14:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622169

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:31:17

Generated On: 10 Jun 2021 09:14:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 10 Nov 2020 16:31:17

Generated On: 10 Jun 2021 09:14:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	4 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Nov 2020 16:31:17

Generated On: 10 Jun 2021 09:14:19

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	4 NOV 2020
Time of assessment (00:00-23:59)	07:19 (24 HR)
Vital Signs Date and Time (derived)	4 NOV 2020 07:19
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	90 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3622169

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Nov 2020 16:31:17

Generated On: 10 Jun 2021 09:14:19

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.

US3622169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Nov 2020 16:31:17

Generated On: 10 Jun 2021 09:14:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 NOV 2020

Collection time (00:00-23:59)

07:35 (24 HR)

Collection date and time (derived)

4 NOV 2020 07:35

US3622169

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 10 Nov 2020 16:31:17

Generated On: 10 Jun 2021 09:14:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

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	10 NOV 2020 19:23:09
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3622169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

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

16 NOV 2020 21:39:06

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

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](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 11:02:36

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	False
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
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 ☒
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Date and time of submission	05 DEC 2020 23:33:53
Patient Cloud Open Date & Time	04 DEC 2020 00:01
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US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

DAY 96

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

11 DEC 2020 14:23:57

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

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](#)

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

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

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

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](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

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 ☒ 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 JAN 2021 18:31:00
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

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 ☒ 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	11 JAN 2021 23:15:25
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

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

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3622169

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 15:06:31

Generated On: 10 Jun 2021 09:14:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622169

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:06:31

Generated On: 10 Jun 2021 09:14:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622169

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 14 Jan 2021 15:06:31

Generated On: 10 Jun 2021 09:14:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3622169

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 14 Jan 2021 15:06:31

Generated On: 10 Jun 2021 09:14:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3622169

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Jan 2021 15:06:30

Generated On: 10 Jun 2021 09:14:19

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

AEID

Adverse event

WORSENING DYSPNEA

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)

29 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)

21 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

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

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

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

AEID

Adverse event

NASAL CONGESTION

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)

29 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)

21 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

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

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

US3622169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

AEID	USA-US085-2020-MRNA-1273-P30 1000004
Adverse event	PNEUMONIA
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)	6 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)	4 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	6 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	4 JAN 2021
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

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

US3622169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

PARTICIPANT WAS INITIALLY CONTACTED FOR MONTH 3 SAFETY CALL ON DECEMBER 3RD, 2020 AND REPORTED NASAL CONGESTION AND WORSENING DYSPNEA SINCE NOVEMBER 29TH, 2020. AT THAT TIME, PARTICIPANT WAS TOLD TO COME IN FOR AN ILLNESS VISIT, BUT STATES THEY WOULD NOT BE ABLE TO COME IN AND RESCHEDULED FOR DECEMBER 4TH, 2020. HOWEVER, PARTICIPANT DID NOT COME ON DECEMBER 4TH, 2020. PARTICIPANT WAS CONTACTED ON DECEMBER 4TH, 2020 AFTER MISSING THEIR SCHEDULED ILLNESS VISIT AND REPORTED SYMPTOMS CONTINUED. PARTICIPANT WAS THEN OFFERED A HOME ILLNESS VISIT, BUT REFUSED AND INSISTED ON COMING IN ON MONDAY, DECEMBER 7TH, 2020. ON DECEMBER 7TH, 2020, PARTICIPANT WAS CONTACTED REGARDING THEIR MISSED SCHEDULED ILLNESS VISIT, TO WHICH THEY INFORMED US THEY WERE HOSPITALIZED SINCE DECEMBER 6TH, 2020. PARTICIPANT STATES THEY WERE DIAGNOSED WITH PNEUMONIA AND STARTED

US3622169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

WITH O2 AND IV ANTIBIOTICS,
BUT DO NOT RECALL EITHER
DOSE.

UPDATE: ON DECEMBER 06,
2020 THE PARTICIPANT WENT
TO NORTHSORE MEDICAL
CENTER ER WITH CHIEF
COMPLAINT OF SHORTNESS OF
BREATH, WEAKNESS, AND
ABDOMINAL PAIN X 3 DAYS.
THE PARTICIPANT WAS
ADMITTED FOR PNEUMONIA.
IN ADDITION, CT SCAN DONE
ON DECEMBER 06, 2020
REVEALED LIVER LESIONS
AND MULTIPLE LUNG
NODULES SUGGESTIVE OF
HEPATOCELLULAR
CARCINOMA WITH LUNG
METASTASES. METASTATIC
HEPATOCELLULAR
CARCINOMA WAS CONFIRMED
WITH CT GUIDED LIVER
BIOPSY ON DECEMBER 30, 2020.
THE PARTICIPANT WAS
DISCHARGED ON JANUARY 4,
2021. WE HAVE RECEIVED
ONLY PARTIAL MEDICAL
RECORDS FROM THIS
ADMISSION BUT HAVE
REQUESTED FULL MEDICAL
RECORDS TO BE SENT. ONCE
WE RECEIVE FULL MEDICAL
RECORDS, WE WILL UPDATE
ADMISSION INFORMATION.

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

US3622169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

AEID	USA-US085-2020-MRNA-1273-P30 1000004
Adverse event	METASTATIC HEPATOCELLULAR CARCINOMA
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)	30 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)	4 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	True
Hospital Admission Date (dd MMM yyyy)	6 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	4 JAN 2021
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

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

US3622169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

AFTER REVIEW OF MEDICAL RECORDS RECEIVED IT WAS FOUND THAT ON DECEMBER 06, 2020 THE PARTICIPANT WENT TO NORTHSORE MEDICAL CENTER ER WITH CHIEF COMPLAINT OF SHORTNESS OF BREATH, WEAKNESS, AND ABDOMINAL PAIN X 3 DAYS. THE PARTICIPANT WAS ADMITTED TO THE ICU ON DECEMBER 06, 2021. DIAGNOSES INCLUDED PNEUMONIA, DYSPNEA, AND HYPOCALCEMIA. CT SCAN DONE ON DECEMBER 06, 2020 REVEALED LIVER LESIONS AND MULTIPLE LUNG NODULES SUGGESTIVE OF HEPATOCELLULAR CARCINOMA WITH LUNG METASTASES. METASTATIC HEPATOCELLULAR CARCINOMA WAS CONFIRMED WITH CT GUIDED LIVER BIOPSY ON DECEMBER 30, 2020. HE WAS FOUND TO HAVE A LARGE RIGHT PLEURAL EFFUSION AND UNDERWENT RIGHT THORACENTESIS ON 12/11/2020 AND RIGHT PLEURAL DRAIN PLACEMENT UNDER U/S GUIDANCE ON 12/15/2020. THE PARTICIPANT WAS DISCHARGED FROM THE HOSPITAL ON JANUARY 4, 2021. HOSPITAL RECORDS RECEIVED

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

TO DATE DO NOT SHOW WHEN
THE PATIENT WAS
DISCHARGED FROM ICU.
MULTIPLE REQUESTS HAVE
BEEN MADE FOR DISCHARGE
SUMMARY AND PHYSICIAN
PROGRESS NOTES AND STILL
HAVE NOT BEEN RECEIVED.

RELEVANT LABS INCLUDE:

12/06/2020 PLATELETS 99 (L),
CALCIUM 8.4 (L), ALK PHOS 280
(H), TOTAL BILI 1.9 (H), ALT 55
(H), AST 94 (H)

12/28/2020 SODIUM 131 (L),
CALCIUM 8.0 (L), AST 7.2 (H), M
PNEUMO IGM POSITIVE, SARS
AG NEGATIVE, COVID 19 PCR
NEGATIVE

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)

Generated On: 10 Jun 2021 09:14:19

AEID	USA-US085-2020-MRNA-1273-P30 1000004
Adverse event	WORSENING METASTATIC HEPATOCELLULAR CARCINOMA
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 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)	21 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	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	21 JAN 2021
Admitted to ICU?	Yes ☒ No ☐ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (5)

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Number of Days in ICU	4
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☒ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

BASED ON MEDICAL RECORDS
OBTAINED, PARTICIPANT
WENT INTO
CARDIOPULMONARY ARREST
AND EXPIRED ON JANUARY 21,
2021.

UPDATE: THE PARTICIPANT
WENT TO THE HOSPITAL ON
JANUARY 16, 2021. CHIEF
COMPLAINT WAS MULTIPLE
SYNCOPAL EPISODES,
WORSENING EDEMA,
WORSENING SHORTNESS OF
BREATH, RIGHT UPPER
QUADRANT PAIN, AND
FATIGUE. HE WAS ADMITTED
TO ICU AND WENT INTO
CARDIOPULMONARY ARREST
ON JANUARY 21, 2021. WE ARE
AWAITING FULL MEDICAL
RECORDS TO REVIEW AND
UPDATE INFORMATION.

UPDATE (PI NOTES):
DISCUSSED WITH TEAM
MONITOR, SECOND ADMISSION
PRIMARY DIAGNOSIS IS
WORSENING/EXACERBATION
OF METASTATIC
HEPATOCELLULAR
CARCINOMA. ALL
SUBSEQUENT HOSPITAL
EVENTS INCLUDING
ANASARCA, SEPSIS, DEATH
ARE SECONDARY TO THIS
DIAGNOSIS. WILL CHANGE SAE

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Folder: Adverse Events

Form: Adverse Events (5)

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TERM TO WORSENING
METASTATIC
HEPATOCELLULAR
CARCINOMA RATHER THAN
CARDIOPULMONARY ARREST.
OTHER AES TO BE ENTERED AS
ALIGN TO CONMEDS (E.G.,
ANTIBIOTICS).

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 (6)

Generated On: 10 Jun 2021 09:14:19

AEID	
Adverse event	SEPSIS
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 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)	21 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	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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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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Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication FLUID RETENTION

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 (1)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐
No ☒

Indication FLUID RETENTION

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 (2)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify ANNUALLY

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) 09 Apr 2021 19:56:13

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	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication DYSPNEA

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 (4)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication 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 (5)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication SOLUMEDROL

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication DUONEB

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

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 ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	NEBULIZER	
Start date (dd MMM yyyy)	6 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	04 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

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) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	6 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	22 DEC 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication CALCIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

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 (9)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication 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 (10)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	15 DEC 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication ZINC SULFATE

Prophylaxis Yes ☒
No ☐

Indication VITAMIN SUPPLEMENTATION

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 (11)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	04 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication VITAMIN SUPPLEMENTATION

Dose per administration 1,000

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) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	04 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication IOPAMIDOL (ISOVUE)

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

Dose per administration 370

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 09 DEC 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

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 (14)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 22 DEC 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		04 JAN 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

Dose per administration 5,000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	6 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	11 DEC 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication VITAMIN D3

Prophylaxis Yes ☒
No ☐

Indication VITAMIN SUPPLEMENTATION

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		7 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 4 JAN 2021		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication 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 (18)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		3 JAN 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication LACTULOSE

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

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 (19)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 4 JAN 2021		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication ROCEPHIN

Prophylaxis Yes ☐
No ☒

Indication 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 (20)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	11 DEC 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication QUETIAPINE

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

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 (21)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 3 JAN 2021		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN (ACCORDING TO
MEDICAL RECORDS)

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	9 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		3 JAN 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication CODEINE-GUAIFENESIN

Prophylaxis Yes ☐
No ☒

Indication COUGH

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 (23)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 4 JAN 2021		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication NADOLOL

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

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 (24)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	31 DEC 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication HUMAN ALBUMIN

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

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 (25)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	22 DEC 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication ZOSYN

Prophylaxis Yes ☐
No ☒

Indication 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 (26)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	23 DEC 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

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 (27)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	26 DEC 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	4 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication FAMOTIDINE

Prophylaxis Yes ☒
No ☐

Indication REFLUX PREVENTION

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 (29)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	6 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		04 JAN 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication MIDODRINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTENSION

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 (30)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	4 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 750

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 (31)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		3 JAN 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication SOLUMEDROL

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	6 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	11 DEC 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication OXYGEN

Prophylaxis Yes ☐
No ☒

Indication DYSPNEA, PNEUMONIA

Dose per administration UNKNOWN

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

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) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	NRBM(NON REBREATH MASK)	
Start date (dd MMM yyyy)	6 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	4 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication RIFAXIMIN

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

Dose per administration 550

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) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 20 JAN 2021		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

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 (35)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	18 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication DAPTOMYCIN

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

Dose per administration 950

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 20 JAN 2021		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication MICAFUNGIN

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

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 (37)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication LASIX

Prophylaxis Yes ☐
No ☒

Indication METASTATIC
HEPATOCELLULAR
CARCINOMA

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 (38)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		10 JAN 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication ONDANSETRON

Prophylaxis Yes ☒
No ☐

Indication NAUSEA PREVENTION

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	21 JAN 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication ALBUMIN 5%

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

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 (40)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		17 JAN 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN (ACCORDING TO
MEDICAL RECORDS)

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 (41)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	IV PUSH	
Start date (dd MMM yyyy)	19 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	19 JAN 2021	
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication SODIUM BICARBONATE

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

Dose per administration 1300

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 (42)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication SODIUM BICARBONATE

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

Dose per administration 50

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 (43)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	19 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication METASTATIC
HEPATOCELLULAR
CARCINOMA

Dose per administration 0.3

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

HOUR CONTINUOUS

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) 09 Apr 2021 19:56:13

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	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		21 JAN 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication ALBUMIN 25%

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

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

EVERY 8 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 (45)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 20 JAN 2021		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication CEFEPIIME

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

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

EVERY 8 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 (46)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		18 JAN 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication FLAGYL

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

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

EVERY 8 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 (47)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication LACTULOSE

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

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 (48)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication VASOPRESSIN

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

Dose per administration 0.04

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 MIN CONTINUOUS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	18 JAN 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication MEROPENEM

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

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

EVERY 8 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 (50)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	18 JAN 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication NOREPINEPHRINE

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

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

MIN CONTINUOUS

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)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication OCETREOTIDE

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

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

HOUR CONTINUOUS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	17 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication PEPCID

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

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 (53)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication LOVENOX

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF BLOOD CLOTS

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 (54)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	18 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	20 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication GLYCOPYRROLATE

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN (ACCORDING TO
MEDICAL RECORDS)

Dose per administration 0.2

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

EVERY 6 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		21 JAN 2021
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication NYSTATIN TOPICAL

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	21 JAN 2021	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 09 Apr 2021 19:56:13

Generated On: 10 Jun 2021 09:14:19

Name of Medication ALBUTEROL-IPRATROPIUM

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

Dose per administration 1

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

If dose unit is Other, specify INHALATION

Frequency once daily ☐
twice 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 6 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 (57)

Data signed: (b) (4) 09 Apr 2021 19:56:13

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	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify		NEBULIZER
Start date (dd MMM yyyy)		20 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		21 JAN 2021
Was this medication taken for solicited event?		Yes ☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 20:13:24

Generated On: 10 Jun 2021 09:14:19

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) 12 Mar 2021 13:13:37

Generated On: 10 Jun 2021 09:14:19

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
06 DEC 2020	X-RAY	Diagnostic	
06 DEC 2020	EKG	Diagnostic	
07 DEC 2020	CHEST X-RAY	Diagnostic	
09 DEC 2020	CHEST X-RAY	Diagnostic	
10 DEC 2020	CHEST X-RAY	Diagnostic	
11 DEC 2020	CHEST X-RAY	Diagnostic	
13 DEC 2020	CHEST X-RAY	Diagnostic	
14 DEC 2020	CHEST X-RAY	Diagnostic	
15 DEC 2020	CHEST X-RAY	Diagnostic	
19 DEC 2020	CHEST X-RAY	Diagnostic	
21 DEC 2020	CHEST X-RAY	Diagnostic	
23 DEC 2020	CHEST X-RAY	Diagnostic	
24 DEC 2020	CHEST X-RAY	Diagnostic	
25 DEC 2020	CHEST X-RAY	Diagnostic	
26 DEC 2020	CHEST X-RAY	Diagnostic	
28 DEC 2020	CHEST X-RAY	Diagnostic	
29 DEC 2020	CHEST X-RAY	Diagnostic	
31 DEC 2020	CHEST X-RAY	Diagnostic	
01 JAN 2021	CHEST X-RAY	Diagnostic	
03 JAN 2021	CHEST X-RAY	Diagnostic	
04 JAN 2021	CHEST X-RAY	Diagnostic	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Data signed: (b) (4) 12 Mar 2021 13:13:37

Generated On: 10 Jun 2021 09:14:19

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
07 DEC 2020	ECHOCARDIOGRAM	Diagnostic	
31 DEC 2020	ECHOCARDIOGRAM	Diagnostic	
27 DEC 2020	CTA CHEST	Diagnostic	
06 DEC 2020	ABDOMINAL ULTRASOUND	Diagnostic	
30 DEC 2020	CT GUIDED LIVER BIOPSY	Diagnostic	
15 DEC 2020	RIGHT PLEURAL DRAIN PLACEMENT UNDER U/S GUIDANCE	Diagnostic	
11 DEC 2020	RIGHT THORACENTESIS	Diagnostic	
09 DEC 2020	CT ABD/PELVIS W/VO CONTRAST	Diagnostic	
26 DEC 2020	VENOUS DUPLEX ULTRASOUND UE RIGHT	Diagnostic	
16 JAN 2021	CT CHEST, ABDOMEN, PELVIS	Diagnostic	
17 JAN 2021	CT ABDOMEN PELVIS W/VO CONTRAST	Diagnostic	
16 JAN 2021	ABDOMINAL ULTRASOUND	Diagnostic	
18 JAN 2021	CHEST X-RAY	Diagnostic	
16 JAN 2021	CHEST X-RAY	Diagnostic	
16 JAN 2021	CENTRAL VENOUS LANE PLACEMENT	Diagnostic	

PRODUCTION RELEASE (v12.003 EAB) (1725)

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US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (37)

Data signed: (b) (4) 12 Mar 2021 13:13:37

Generated On: 10 Jun 2021 09:14:19

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
19 JAN 2021	ECHOCARDIOGRAM	Diagnostic	
06 DEC 2020	CTA CHEST	Diagnostic	

US3622169

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 12 Feb 2021 14:05:21

Generated On: 10 Jun 2021 09:14:19

Date of study discontinuation/completion (dd MMM yyyy) 21 JAN 2021

Reason for discontinuation

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

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

If reason for discontinuation is Death, main cause of death

Adverse event	☒
Unknown	☐
Other	☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy) 21 JAN 2021

Was autopsy performed?

Yes	☐
No	☐
Unknown	☒

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 12 Mar 2021 13:13:37

Generated On: 10 Jun 2021 09:14:19

SAEID	USA-US085-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Mar 2021 13:13:37

Generated On: 10 Jun 2021 09:14:19

SAEID	USA-US085-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	07/DEC/2020 12:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Mar 2021 13:13:37

Generated On: 10 Jun 2021 09:14:19

SAEID	USA-US085-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	08/DEC/2020 00:24
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Mar 2021 13:13:37

Generated On: 10 Jun 2021 09:14:19

SAEID	USA-US085-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	27/JAN/2021 10:25
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

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Mar 2021 13:13:37

Generated On: 10 Jun 2021 09:14:19

SAEID	USA-US085-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	18/FEB/2021 15:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Mar 2021 13:13:37

Generated On: 10 Jun 2021 09:14:19

SAEID	USA-US085-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	19/FEB/2021 09:44
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

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 12 Mar 2021 13:13:37

Generated On: 10 Jun 2021 09:14:19

SAEID	USA-US085-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	22/FEB/2021 14:25
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

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Data signed: (b) (4) 12 Mar 2021 13:13:37

Generated On: 10 Jun 2021 09:14:19

SAEID	USA-US085-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	23/FEB/2021 09:08
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

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Data signed: (b) (4) 12 Mar 2021 13:13:37

Generated On: 10 Jun 2021 09:14:19

SAEID	USA-US085-2020-MRNA-1273-P301000004
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☒ No ☐
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	10/MAR/2021 07:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 14 Jan 2021 15:06:31

Generated On: 10 Jun 2021 09:14:19

SAEID	USA-US085-2020-MRNA-1273-P301000005
Serious	Yes ☐ No ☒
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 14 Jan 2021 15:06:31

Generated On: 10 Jun 2021 09:14:19

SAEID USA-US085-2020-MRNA-1273-P30
1000005

Serious Yes ☐
No ☒

Death Yes ☐
No ☒

Life threatening Yes ☐
No ☒

Requires inpatient or prolongation of existing Hospitalization Yes ☐
No ☒

Persistent or significant disability or incapacity Yes ☐
No ☒

Congenital anomaly or birth defect Yes ☐
No ☒

Other medically important event Yes ☐
No ☒

Investigator's First Name SUSANNE

Investigator's Last Name DOBLECKI-LEWIS

Site Address: Street 1120 NW 14TH STREET

Site Address: City MIAMI

Site Address: State FL

Site Address: Postal Code 33136

Investigator Country US

E2B Transmit Flag (Derived/Hidden)

Date of submission (Pre-filled from custom function)

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

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 28 Jan 2021 15:09:45

Generated On: 10 Jun 2021 09:14:19

SAEID	USA-US085-2021-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Jan 2021 15:09:45

Generated On: 10 Jun 2021 09:14:19

SAEID	USA-US085-2021-MRNA-1273-P301000008
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	SUSANNE
Investigator's Last Name	DOBLECKI-LEWIS
Site Address: Street	1120 NW 14TH STREET
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33136
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	27/JAN/2021 10:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3622169 (Prod: University of Miami)

US3622169

Form: Participant Creation

Generated On: 10 Jun 2021 09:14:19

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:11:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'US3622169'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 14:39:47

US3622169

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:08
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:23:00

US3622169

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:08
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 14:39:48

US3622169

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:08
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Sep 2020 15:23:00

US3622169

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'SCRN'	System	09 Sep 2020 15:23:00

US3622169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:48
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered (b) (6) 1964'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 14:39:49

US3622169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:19

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:48
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '56'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:59:08

US3622169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:19

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'YEARS'	System	10 Sep 2020 15:59:08

US3622169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '56'	System	09 Sep 2020 15:23:12

US3622169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:19

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:48
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:59:08

US3622169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:19

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:48
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	10 Sep 2020 15:59:08

US3622169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:19

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:48
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:59:08

US3622169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:19

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:48
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:59:08

US3622169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:19

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:48
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:59:08

US3622169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:48
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:59:08

US3622169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:48
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 15:59:08

US3622169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:48
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:59:08

US3622169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:19

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:48
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:59:08

US3622169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:19

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:48
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:59:08

US3622169

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:14:19

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:40:48
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:59:08

US3622169

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:19

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:41:01
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '9 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 15:23:12

US3622169

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'Sep 2020'	System	09 Sep 2020 15:23:12

US3622169

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '2020'	System	09 Sep 2020 15:23:12

US3622169

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:19

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:41:01
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	09 Sep 2020 15:23:12

US3622169

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:41:01
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 15:23:12

US3622169

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:19

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:41:01
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:23:12

US3622169

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:41:01
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:23:12

US3622169

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:41:01
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4), (b) (6)	09 Sep 2020 15:23:12

US3622169

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:41:01
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 14:39:48

US3622169

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:14:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '1'	System	09 Sep 2020 15:23:19

US3622169

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:41:12
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 15:23:19

US3622169

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:14:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:41:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:01:03

US3622169

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:51:54
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'no HTN tx reported' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 18:33:19
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 05:18:09
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 21:03:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 21:03:43
Data point term sent to Coder	System	10 Sep 2020 21:02:10
User entered 'Hypertension'	(b) (4), (b) (6)	10 Sep 2020 21:01:31

US3622169

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'un UNK 1985' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 21:02:57
User entered '9 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 21:01:31

US3622169

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:01:31

US3622169

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:01:31

US3622169

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:01:31

US3622169

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:01:31

US3622169

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'Jan 1985'	System	10 Sep 2020 21:02:57
User entered 'Sep 2020'	System	10 Sep 2020 21:01:31

US3622169

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '1985'	System	10 Sep 2020 21:02:57
User entered '2020'	System	10 Sep 2020 21:01:31

US3622169

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered empty.	System	10 Sep 2020 21:01:31

US3622169

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered empty.	System	10 Sep 2020 21:01:31

US3622169

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 21:03:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 21:03:44
Data point term sent to Coder	System	10 Sep 2020 21:03:11
User entered 'Diabetes'	(b) (4), (b) (6)	10 Sep 2020 21:02:25

US3622169

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'un UNK 2014'	(b) (4), (b) (6)	10 Sep 2020 21:02:25

US3622169

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:02:25

US3622169

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:02:25

US3622169

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:02:25

US3622169

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:02:25

US3622169

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'Jan 2014'	System	10 Sep 2020 21:02:25

US3622169

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '2014'	System	10 Sep 2020 21:02:25

US3622169

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered empty.	System	10 Sep 2020 21:02:25

US3622169

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered empty.	System	10 Sep 2020 21:02:25

US3622169

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 08:10:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 08:10:52
Data point term sent to Coder	System	10 Sep 2020 21:05:13
User entered 'Severe obesity (BMI 49.6)'	(b) (4), (b) (6)	10 Sep 2020 21:04:19

US3622169

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'un UNK 2008'	(b) (4), (b) (6)	10 Sep 2020 21:04:19

US3622169

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:04:19

US3622169

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:04:19

US3622169

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:04:19

US3622169

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:04:19

US3622169

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'Jan 2008'	System	10 Sep 2020 21:04:19

US3622169

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '2008'	System	10 Sep 2020 21:04:19

US3622169

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered empty.	System	10 Sep 2020 21:04:19

US3622169

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered empty.	System	10 Sep 2020 21:04:19

US3622169

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:19

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Dyspnea - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 21:05:46
Data point term sent to Coder	(b) (4)	
User entered 'Dyspnea'	System	10 Sep 2020 21:05:14
	(b) (4), (b) (6)	10 Sep 2020 21:05:12

US3622169

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'un UNK 2018'	(b) (4), (b) (6)	10 Sep 2020 21:05:12

US3622169

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:05:12

US3622169

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:05:12

US3622169

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:05:12

US3622169

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:05:12

US3622169

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'Jan 2018'	System	10 Sep 2020 21:05:12

US3622169

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '2018'	System	10 Sep 2020 21:05:12

US3622169

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered empty.	System	10 Sep 2020 21:05:12

US3622169

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered empty.	System	10 Sep 2020 21:05:12

US3622169

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:19

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Total fluid volume increased, PT: Fluid retention, LLT: Fluid retention - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 21:06:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 21:06:48
Data point term sent to Coder	System	10 Sep 2020 21:06:14
User entered 'Fluid retention'	(b) (4), (b) (6)	10 Sep 2020 21:05:58

US3622169

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'un UNK 1991'	(b) (4), (b) (6)	10 Sep 2020 21:05:58

US3622169

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:05:58

US3622169

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:05:58

US3622169

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:05:58

US3622169

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:42:30
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 21:05:58

US3622169

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'Jan 1991'	System	10 Sep 2020 21:05:58

US3622169

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '1991'	System	10 Sep 2020 21:05:58

US3622169

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered empty.	System	10 Sep 2020 21:05:58

US3622169

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered empty.	System	10 Sep 2020 21:05:58

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:07:59

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '9 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 21:07:59

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '09:22'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:07:59

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '9 Sep 2020 09:22'	System	10 Sep 2020 21:07:59

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '67' in	(b) (4), (b) (6)	10 Sep 2020 21:07:59
DataPoint set to visible.	System	09 Sep 2020 15:23:19

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '317' lb	(b) (4), (b) (6)	10 Sep 2020 21:07:59
DataPoint set to visible.	System	09 Sep 2020 15:23:19

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '49.75303'	System	10 Sep 2020 21:07:59
DataPoint set to visible.	System	09 Sep 2020 15:23:19

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'kg/m2'	System	10 Sep 2020 21:07:59
DataPoint set to visible.	System	09 Sep 2020 15:23:19

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Sep 2020 21:07:59

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:07:59

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:07:59

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Sep 2020 21:07:59

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'bpm'	System	10 Sep 2020 21:07:59

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Sep 2020 21:07:59

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'breaths/min'	System	10 Sep 2020 21:07:59

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Sep 2020 21:07:59

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'mmHg'	System	10 Sep 2020 21:07:59

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:32
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Sep 2020 21:07:59

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'mmHg'	System	10 Sep 2020 21:07:59

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47

US3622169

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47

US3622169

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:44
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:08:38

US3622169

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:44
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '9 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 21:08:38

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

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)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

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)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

[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)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

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)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

[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)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

[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)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

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)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

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)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Disabled, socially active'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

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)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

[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)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

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)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:14:19

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:43:52
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:09:39

US3622169

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:44:26
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 15:23:32

US3622169

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:44:26
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '9 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 15:23:32

US3622169

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:44:26
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Sep 2020 15:23:32

US3622169

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'VISIT1'	System	09 Sep 2020 15:23:32

US3622169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:44:37
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 14:39:56

US3622169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:44:37
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '146057'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 14:39:56

US3622169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:44:37
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 14:39:56

US3622169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:19

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)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:44:37
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:12:04

US3622169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:19

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)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:44:37
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:12:04

US3622169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:44:37
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:12:04

US3622169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:44:37
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:12:04

US3622169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:19

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:44:37
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:12:04

US3622169

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:44:37
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'No (N)'	(b) (4) Junlin Long (b) (4)	29 Sep 2020 12:16:39
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 05:47:06
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:47:05

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '9 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '09:22'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '9 Sep 2020 09:22'	System	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '91'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'bpm'	System	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '20'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'breaths/min'	System	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '121'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'mmHg'	System	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '84'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'mmHg'	System	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:19

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:14:19

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered missing code ND - Not Done.	(b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '9 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '11:50'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '9 Sep 2020 11:50'	System	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '83'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'bpm'	System	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '24'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'breaths/min'	System	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '114'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'mmHg'	System	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:10
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '80'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'mmHg'	System	10 Sep 2020 21:17:53

US3622169

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:37
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 21:18:26

US3622169

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:37
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 21:18:26

US3622169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:45
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:24:01

US3622169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:45
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:24:01

US3622169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

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)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:45
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:24:01

US3622169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 15:24:01

US3622169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:45
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '9 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 15:24:01

US3622169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:45
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '11:12'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:24:01

US3622169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '9 Sep 2020 11:12'	System	09 Sep 2020 15:24:01

US3622169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:45
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	09 Sep 2020 15:24:01

US3622169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:45
User entered 'ONCE'	System	09 Sep 2020 15:24:01

US3622169

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 15:24:01

US3622169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:57
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:18:52

US3622169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:57
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:18:52

US3622169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:45:57
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '09:30'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:18:52

US3622169

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '9 Sep 2020 09:30'	System	10 Sep 2020 21:18:52

US3622169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:14:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:46:08
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:19:17

US3622169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Sep 2020 21:19:17

US3622169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:46:08
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:19:17

US3622169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:46:08
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '09:35'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:19:17

US3622169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '9 Sep 2020 09:35'	System	10 Sep 2020 21:19:17

US3622169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Sep 2020 21:19:17

US3622169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:46:08
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:19:17

US3622169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:46:08
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:19:17

US3622169

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered empty.	System	10 Sep 2020 21:19:17

US3622169

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:46:19
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:19:25

US3622169

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '1'	System	10 Sep 2020 21:19:25

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:56:11', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '8357af19-3cb7-4d7f-b921-f9444e2421d2'	System	09 Sep 2020 15:56:55
User entered 'Yes (Y)'	System	09 Sep 2020 15:56:55

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:56:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '8357af19-3cb7-4d7f-b921-f9444e2421d2'	System	09 Sep 2020 15:56:55
User entered '98.5'	System	09 Sep 2020 15:56:55

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:56:36', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '8357af19-3cb7-4d7f-b921-f9444e2421d2'	System	09 Sep 2020 15:56:55
User entered 'No (N)'	System	09 Sep 2020 15:56:55

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:56:51', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '8357af19-3cb7-4d7f-b921-f9444e2421d2'	System	09 Sep 2020 15:56:55
User entered '09 Sep 2020 11:56'	System	09 Sep 2020 15:56:55

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '09 Sep 2020 11:32'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '09 Sep 2020 14:02'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:09:39', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '4e21915b-7688-40f7-b03a-6536a08630a7'	System	09 Sep 2020 23:10:17
User entered 'Yes (Y)'	System	09 Sep 2020 23:10:17

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:09:58', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '4e21915b-7688-40f7-b03a-6536a08630a7' User entered '98.3'	System	09 Sep 2020 23:10:17

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:10:04', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '4e21915b-7688-40f7-b03a-6536a08630a7'	System	09 Sep 2020 23:10:17
User entered 'No (N)'	System	09 Sep 2020 23:10:17

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:10:12', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '4e21915b-7688-40f7-b03a-6536a08630a7'	System	09 Sep 2020 23:10:17
User entered '09 Sep 2020 19:10'	System	09 Sep 2020 23:10:17

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '09 Sep 2020 14:57'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 2'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:00:42', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5be97bb1-3294-4342-a037-f5d678e8532d'	System	10 Sep 2020 23:01:12
User entered 'Yes (Y)'	System	10 Sep 2020 23:01:12

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:00:50', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5be97bb1-3294-4342-a037-f5d678e8532d' User entered '98.8'	System	10 Sep 2020 23:01:12
	System	10 Sep 2020 23:01:12

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:00:57', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5be97bb1-3294-4342-a037-f5d678e8532d'	System	10 Sep 2020 23:01:12
User entered 'No (N)'	System	10 Sep 2020 23:01:12

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:01:08', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5be97bb1-3294-4342-a037-f5d678e8532d'	System	10 Sep 2020 23:01:12
User entered '10 Sep 2020 19:01'	System	10 Sep 2020 23:01:12

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 3'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T18:58:09', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '62107307-c3f6-4317-9f11-24b95ca32d34'	System	11 Sep 2020 22:58:49
User entered 'Yes (Y)'	System	11 Sep 2020 22:58:49

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T18:58:19', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '62107307-c3f6-4317-9f11-24b95ca32d34'	System	11 Sep 2020 22:58:49
User entered '99.2'	System	11 Sep 2020 22:58:49

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T18:58:24', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '62107307-c3f6-4317-9f11-24b95ca32d34'	System	11 Sep 2020 22:58:49
User entered 'No (N)'	System	11 Sep 2020 22:58:49

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T18:58:36', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '62107307-c3f6-4317-9f11-24b95ca32d34'	System	11 Sep 2020 22:58:49
User entered '11 Sep 2020 18:58'	System	11 Sep 2020 22:58:49

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 4'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:02:08', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '378d3db3-1f30-4809-bf62-42e446f10b45'	System	12 Sep 2020 23:02:30
User entered 'Yes (Y)'	System	12 Sep 2020 23:02:30

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:02:13', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '378d3db3-1f30-4809-bf62-42e446f10b45'	System	12 Sep 2020 23:02:30
User entered '98.3'	System	12 Sep 2020 23:02:30

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:02:19', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '378d3db3-1f30-4809-bf62-42e446f10b45'	System	12 Sep 2020 23:02:30
User entered 'No (N)'	System	12 Sep 2020 23:02:30

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:02:25', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '378d3db3-1f30-4809-bf62-42e446f10b45'	System	12 Sep 2020 23:02:30
User entered '12 Sep 2020 19:02'	System	12 Sep 2020 23:02:30

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 5'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:06:21', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '43ad7e3f-cfdf-4220-b9e9-a84ee064f0be'	System	13 Sep 2020 23:06:41
User entered 'Yes (Y)'	System	13 Sep 2020 23:06:41

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:06:27', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '43ad7e3f-cfdf-4220-b9e9-a84ee064f0be'	System	13 Sep 2020 23:06:41
User entered '98.2'	System	13 Sep 2020 23:06:41

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:06:32', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '43ad7e3f-cfdf-4220-b9e9-a84ee064f0be'	System	13 Sep 2020 23:06:41
User entered 'No (N)'	System	13 Sep 2020 23:06:41

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:06:37', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '43ad7e3f-cfdf-4220-b9e9-a84ee064f0be'	System	13 Sep 2020 23:06:41
User entered '13 Sep 2020 19:06'	System	13 Sep 2020 23:06:41

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 6'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:01:55', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '884f8e51-4ae6-46dd-a8df-dd4032508f2a'	System	14 Sep 2020 23:02:17
User entered 'Yes (Y)'	System	14 Sep 2020 23:02:17

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:05', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '884f8e51-4ae6-46dd-a8df-dd4032508f2a'	System	14 Sep 2020 23:02:17
User entered '98.2'	System	14 Sep 2020 23:02:17

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:10', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '884f8e51-4ae6-46dd-a8df-dd4032508f2a'	System	14 Sep 2020 23:02:17
User entered 'No (N)'	System	14 Sep 2020 23:02:17

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:13', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '884f8e51-4ae6-46dd-a8df-dd4032508f2a'	System	14 Sep 2020 23:02:17
User entered '14 Sep 2020 19:02'	System	14 Sep 2020 23:02:17

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 7'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:50:11', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'd582f762-a0a3-4e39-8592-7f704b9fa22c'	System	15 Sep 2020 22:50:38
User entered 'Yes (Y)'	System	15 Sep 2020 22:50:38

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:50:19', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'd582f762-a0a3-4e39-8592-7f704b9fa22c'	System	15 Sep 2020 22:50:38
User entered '98.3'	System	15 Sep 2020 22:50:38

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:50:24', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'd582f762-a0a3-4e39-8592-7f704b9fa22c'	System	15 Sep 2020 22:50:38
User entered 'No (N)'	System	15 Sep 2020 22:50:38

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:50:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'd582f762-a0a3-4e39-8592-7f704b9fa22c'	System	15 Sep 2020 22:50:38
User entered '15 Sep 2020 18:50'	System	15 Sep 2020 22:50:38

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:57:11', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '94349ec2-b57e-415e-a5ac-346c31522d98'	System	09 Sep 2020 15:57:47
User entered 'None (1)'	System	09 Sep 2020 15:57:47

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:57:16', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '94349ec2-b57e-415e-a5ac-346c31522d98'	System	09 Sep 2020 15:57:47
User entered 'No (N)'	System	09 Sep 2020 15:57:47

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:57:20', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '94349ec2-b57e-415e-a5ac-346c31522d98'	System	09 Sep 2020 15:57:47
User entered 'No (N)'	System	09 Sep 2020 15:57:47

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:57:32', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '94349ec2-b57e-415e-a5ac-346c31522d98'	System	09 Sep 2020 15:57:47
User entered 'None (1)'	System	09 Sep 2020 15:57:47

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:57:43', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '94349ec2-b57e-415e-a5ac-346c31522d98'	System	09 Sep 2020 15:57:47
User entered '09 Sep 2020 11:57'	System	09 Sep 2020 15:57:47

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '09 Sep 2020 11:32'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '09 Sep 2020 14:02'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:10:23', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'e68e7459-5552-464b-a17e-69255f4899d9'	System	09 Sep 2020 23:10:53
User entered 'None (1)'	System	09 Sep 2020 23:10:53

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:10:29', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'e68e7459-5552-464b-a17e-69255f4899d9'	System	09 Sep 2020 23:10:53
User entered 'No (N)'	System	09 Sep 2020 23:10:53

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:10:33', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'e68e7459-5552-464b-a17e-69255f4899d9'	System	09 Sep 2020 23:10:53
User entered 'No (N)'	System	09 Sep 2020 23:10:53

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:10:43', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'e68e7459-5552-464b-a17e-69255f4899d9'	System	09 Sep 2020 23:10:53
User entered 'None (1)'	System	09 Sep 2020 23:10:53

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:10:49', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'e68e7459-5552-464b-a17e-69255f4899d9'	System	09 Sep 2020 23:10:53
User entered '09 Sep 2020 19:10'	System	09 Sep 2020 23:10:53

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '09 Sep 2020 14:57'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 2'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:01:19', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '34cdb8a3-4990-4089-8e1f-08f440439cb3'	System	10 Sep 2020 23:02:00
User entered 'None (1)'	System	10 Sep 2020 23:02:00

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:01:25', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '34cdb8a3-4990-4089-8e1f-08f440439cb3'	System	10 Sep 2020 23:02:00
User entered 'No (N)'	System	10 Sep 2020 23:02:00

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:01:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '34cdb8a3-4990-4089-8e1f-08f440439cb3'	System	10 Sep 2020 23:02:00
User entered 'No (N)'	System	10 Sep 2020 23:02:00

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:01:39', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '34cdb8a3-4990-4089-8e1f-08f440439cb3'	System	10 Sep 2020 23:02:00
User entered 'None (1)'	System	10 Sep 2020 23:02:00

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:01:47', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '34cdb8a3-4990-4089-8e1f-08f440439cb3'	System	10 Sep 2020 23:02:00
User entered '10 Sep 2020 19:01'	System	10 Sep 2020 23:02:00

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 3'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T18:58:45', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '283f106b-15e4-4123-9d15-79d144b2d652'	System	11 Sep 2020 22:59:49
User entered 'None (1)'	System	11 Sep 2020 22:59:49

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T18:58:51', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '283f106b-15e4-4123-9d15-79d144b2d652'	System	11 Sep 2020 22:59:49
User entered 'No (N)'	System	11 Sep 2020 22:59:49

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T18:58:55', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '283f106b-15e4-4123-9d15-79d144b2d652'	System	11 Sep 2020 22:59:49
User entered 'No (N)'	System	11 Sep 2020 22:59:49

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T18:59:01', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '283f106b-15e4-4123-9d15-79d144b2d652'	System	11 Sep 2020 22:59:49
User entered 'None (1)'	System	11 Sep 2020 22:59:49

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T18:59:26', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '283f106b-15e4-4123-9d15-79d144b2d652'	System	11 Sep 2020 22:59:49
User entered '11 Sep 2020 18:59'	System	11 Sep 2020 22:59:49

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 4'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:02:31', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5cd87144-5023-47df-8883-fdb9b835abf8'	System	12 Sep 2020 23:02:58
User entered 'None (1)'	System	12 Sep 2020 23:02:58

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:02:37', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5cd87144-5023-47df-8883-fdb9b835abf8'	System	12 Sep 2020 23:02:58
User entered 'No (N)'	System	12 Sep 2020 23:02:58

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:02:42', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5cd87144-5023-47df-8883-fdb9b835abf8'	System	12 Sep 2020 23:02:58
User entered 'No (N)'	System	12 Sep 2020 23:02:58

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:02:46', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5cd87144-5023-47df-8883-fdb9b835abf8'	System	12 Sep 2020 23:02:58
User entered 'None (1)'	System	12 Sep 2020 23:02:58

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:02:54', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5cd87144-5023-47df-8883-fdb9b835abf8'	System	12 Sep 2020 23:02:58
User entered '12 Sep 2020 19:02'	System	12 Sep 2020 23:02:58

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 5'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:06:45', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'b92d48fd-485c-4762-ab0f-70a8fa64bf09'	System	13 Sep 2020 23:07:09
User entered 'None (1)'	System	13 Sep 2020 23:07:09

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:06:49', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'b92d48fd-485c-4762-ab0f-70a8fa64bf09'	System	13 Sep 2020 23:07:09
User entered 'No (N)'	System	13 Sep 2020 23:07:09

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:06:53', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'b92d48fd-485c-4762-ab0f-70a8fa64bf09'	System	13 Sep 2020 23:07:09
User entered 'No (N)'	System	13 Sep 2020 23:07:09

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:06:57', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'b92d48fd-485c-4762-ab0f-70a8fa64bf09'	System	13 Sep 2020 23:07:09
User entered 'None (1)'	System	13 Sep 2020 23:07:09

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:07:03', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'b92d48fd-485c-4762-ab0f-70a8fa64bf09'	System	13 Sep 2020 23:07:09
User entered '13 Sep 2020 19:07'	System	13 Sep 2020 23:07:09

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 6'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:18', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '71fb12b0-8b0b-48ed-979e-7eb0e28d0d83'	System	14 Sep 2020 23:02:40
User entered 'None (1)'	System	14 Sep 2020 23:02:40

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:24', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '71fb12b0-8b0b-48ed-979e-7eb0e28d0d83'	System	14 Sep 2020 23:02:40
User entered 'No (N)'	System	14 Sep 2020 23:02:40

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:27', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '71fb12b0-8b0b-48ed-979e-7eb0e28d0d83'	System	14 Sep 2020 23:02:40
User entered 'No (N)'	System	14 Sep 2020 23:02:40

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:31', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '71fb12b0-8b0b-48ed-979e-7eb0e28d0d83'	System	14 Sep 2020 23:02:40
User entered 'None (1)'	System	14 Sep 2020 23:02:40

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:34', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '71fb12b0-8b0b-48ed-979e-7eb0e28d0d83'	System	14 Sep 2020 23:02:40
User entered '14 Sep 2020 19:02'	System	14 Sep 2020 23:02:40

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 7'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:50:37', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ab19872d-384a-415a-94b0-c0bd1aafdc86'	System	15 Sep 2020 22:51:05
User entered 'None (1)'	System	15 Sep 2020 22:51:05

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:50:43', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ab19872d-384a-415a-94b0-c0bd1aafdc86'	System	15 Sep 2020 22:51:05
User entered 'No (N)'	System	15 Sep 2020 22:51:05

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:50:47', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ab19872d-384a-415a-94b0-c0bd1aafdc86'	System	15 Sep 2020 22:51:05
User entered 'No (N)'	System	15 Sep 2020 22:51:05

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:50:52', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ab19872d-384a-415a-94b0-c0bd1aafdc86'	System	15 Sep 2020 22:51:05
User entered 'None (1)'	System	15 Sep 2020 22:51:05

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:50:59', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ab19872d-384a-415a-94b0-c0bd1aafdc86'	System	15 Sep 2020 22:51:05
User entered '15 Sep 2020 18:50'	System	15 Sep 2020 22:51:05

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:57:53', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c195284a-be02-4ee9-9a6f-da9ce5a0bf8d'	System	09 Sep 2020 15:58:38
User entered 'None (0)'	System	09 Sep 2020 15:58:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:57:57', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c195284a-be02-4ee9-9a6f-da9ce5a0bf8d'	System	09 Sep 2020 15:58:38
User entered 'None (0)'	System	09 Sep 2020 15:58:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:58:01', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c195284a-be02-4ee9-9a6f-da9ce5a0bf8d'	System	09 Sep 2020 15:58:38
User entered 'None (0)'	System	09 Sep 2020 15:58:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:58:05', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c195284a-be02-4ee9-9a6f-da9ce5a0bf8d'	System	09 Sep 2020 15:58:38
User entered 'None (0)'	System	09 Sep 2020 15:58:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:58:08', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c195284a-be02-4ee9-9a6f-da9ce5a0bf8d'	System	09 Sep 2020 15:58:38
User entered 'None (0)'	System	09 Sep 2020 15:58:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:58:12', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c195284a-be02-4ee9-9a6f-da9ce5a0bf8d'	System	09 Sep 2020 15:58:38
User entered 'None (0)'	System	09 Sep 2020 15:58:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:58:26', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c195284a-be02-4ee9-9a6f-da9ce5a0bf8d'	System	09 Sep 2020 15:58:38
User entered 'No (N)'	System	09 Sep 2020 15:58:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T11:58:31', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c195284a-be02-4ee9-9a6f-da9ce5a0bf8d'	System	09 Sep 2020 15:58:38
User entered '09 Sep 2020 11:58'	System	09 Sep 2020 15:58:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '09 Sep 2020 11:32'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '09 Sep 2020 14:02'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:10:56', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '828f9338-ad59-4a94-92a0-f96c110aa543'	System	09 Sep 2020 23:11:42
User entered 'None (0)'	System	09 Sep 2020 23:11:42

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:10:59', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '828f9338-ad59-4a94-92a0-f96c110aa543'	System	09 Sep 2020 23:11:42
User entered 'None (0)'	System	09 Sep 2020 23:11:42

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:11:03', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '828f9338-ad59-4a94-92a0-f96c110aa543'	System	09 Sep 2020 23:11:42
User entered 'None (0)'	System	09 Sep 2020 23:11:42

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:11:07', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '828f9338-ad59-4a94-92a0-f96c110aa543'	System	09 Sep 2020 23:11:42
User entered 'None (0)'	System	09 Sep 2020 23:11:42

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:11:11', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '828f9338-ad59-4a94-92a0-f96c110aa543'	System	09 Sep 2020 23:11:42
User entered 'None (0)'	System	09 Sep 2020 23:11:42

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:11:15', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '828f9338-ad59-4a94-92a0-f96c110aa543'	System	09 Sep 2020 23:11:42
User entered 'None (0)'	System	09 Sep 2020 23:11:42

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:11:34', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '828f9338-ad59-4a94-92a0-f96c110aa543'	System	09 Sep 2020 23:11:42
User entered 'No (N)'	System	09 Sep 2020 23:11:42

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-09T19:11:37', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '828f9338-ad59-4a94-92a0-f96c110aa543'	System	09 Sep 2020 23:11:42
User entered '09 Sep 2020 19:11'	System	09 Sep 2020 23:11:42

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '09 Sep 2020 14:57'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 2'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:01:57', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '9d802be9-27bd-4fad-8e22-ca54f1e53f00'	System	10 Sep 2020 23:02:35
User entered 'None (0)'	System	10 Sep 2020 23:02:35

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:02:01', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '9d802be9-27bd-4fad-8e22-ca54f1e53f00'	System	10 Sep 2020 23:02:35
User entered 'None (0)'	System	10 Sep 2020 23:02:35

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:02:04', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '9d802be9-27bd-4fad-8e22-ca54f1e53f00'	System	10 Sep 2020 23:02:35
User entered 'None (0)'	System	10 Sep 2020 23:02:35

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:02:09', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '9d802be9-27bd-4fad-8e22-ca54f1e53f00'	System	10 Sep 2020 23:02:35
User entered 'None (0)'	System	10 Sep 2020 23:02:35

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:02:13', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '9d802be9-27bd-4fad-8e22-ca54f1e53f00'	System	10 Sep 2020 23:02:35
User entered 'None (0)'	System	10 Sep 2020 23:02:35

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:02:16', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '9d802be9-27bd-4fad-8e22-ca54f1e53f00'	System	10 Sep 2020 23:02:35
User entered 'None (0)'	System	10 Sep 2020 23:02:35

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:02:23', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '9d802be9-27bd-4fad-8e22-ca54f1e53f00'	System	10 Sep 2020 23:02:35
User entered 'No (N)'	System	10 Sep 2020 23:02:35

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-10T19:02:26', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '9d802be9-27bd-4fad-8e22-ca54f1e53f00'	System	10 Sep 2020 23:02:35
User entered '10 Sep 2020 19:02'	System	10 Sep 2020 23:02:35

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 3'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T18:59:34', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0a517ef1-e4ed-438e-ac12-4275a9c338f5'	System	11 Sep 2020 23:00:52
User entered 'None (0)'	System	11 Sep 2020 23:00:52

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T18:59:38', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0a517ef1-e4ed-438e-ac12-4275a9c338f5'	System	11 Sep 2020 23:00:52
User entered 'None (0)'	System	11 Sep 2020 23:00:52

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T18:59:41', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0a517ef1-e4ed-438e-ac12-4275a9c338f5'	System	11 Sep 2020 23:00:52
User entered 'None (0)'	System	11 Sep 2020 23:00:52

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T18:59:44', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0a517ef1-e4ed-438e-ac12-4275a9c338f5'	System	11 Sep 2020 23:00:52
User entered 'None (0)'	System	11 Sep 2020 23:00:52

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T18:59:52', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0a517ef1-e4ed-438e-ac12-4275a9c338f5'	System	11 Sep 2020 23:00:52
User entered 'None (0)'	System	11 Sep 2020 23:00:52

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T18:59:55', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0a517ef1-e4ed-438e-ac12-4275a9c338f5'	System	11 Sep 2020 23:00:52
User entered 'None (0)'	System	11 Sep 2020 23:00:52

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T19:00:03', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0a517ef1-e4ed-438e-ac12-4275a9c338f5'	System	11 Sep 2020 23:00:52
User entered 'No (N)'	System	11 Sep 2020 23:00:52

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-11T19:00:20', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0a517ef1-e4ed-438e-ac12-4275a9c338f5'	System	11 Sep 2020 23:00:52
User entered '11 Sep 2020 19:00'	System	11 Sep 2020 23:00:52

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 4'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:03:00', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ed1d1fc1-8c7d-4817-bc82-85ca3bd82969'	System	12 Sep 2020 23:03:37
User entered 'None (0)'	System	12 Sep 2020 23:03:37

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:03:03', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ed1d1fc1-8c7d-4817-bc82-85ca3bd82969'	System	12 Sep 2020 23:03:37
User entered 'None (0)'	System	12 Sep 2020 23:03:37

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:03:06', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ed1d1fc1-8c7d-4817-bc82-85ca3bd82969'	System	12 Sep 2020 23:03:37
User entered 'None (0)'	System	12 Sep 2020 23:03:37

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:03:08', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ed1d1fc1-8c7d-4817-bc82-85ca3bd82969'	System	12 Sep 2020 23:03:37
User entered 'None (0)'	System	12 Sep 2020 23:03:37

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:03:11', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ed1d1fc1-8c7d-4817-bc82-85ca3bd82969'	System	12 Sep 2020 23:03:37
User entered 'None (0)'	System	12 Sep 2020 23:03:37

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:03:13', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ed1d1fc1-8c7d-4817-bc82-85ca3bd82969'	System	12 Sep 2020 23:03:37
User entered 'None (0)'	System	12 Sep 2020 23:03:37

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:03:28', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ed1d1fc1-8c7d-4817-bc82-85ca3bd82969'	System	12 Sep 2020 23:03:37
User entered 'No (N)'	System	12 Sep 2020 23:03:37

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-12T19:03:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ed1d1fc1-8c7d-4817-bc82-85ca3bd82969'	System	12 Sep 2020 23:03:37
User entered '12 Sep 2020 19:03'	System	12 Sep 2020 23:03:37

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 5'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:07:09', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'f5d92c2c-f6ba-4c4b-83bc-eb83aa2ae80c'	System	13 Sep 2020 23:07:38
User entered 'None (0)'	System	13 Sep 2020 23:07:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:07:13', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'f5d92c2c-f6ba-4c4b-83bc-eb83aa2ae80c'	System	13 Sep 2020 23:07:38
User entered 'None (0)'	System	13 Sep 2020 23:07:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:07:16', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'f5d92c2c-f6ba-4c4b-83bc-eb83aa2ae80c'	System	13 Sep 2020 23:07:38
User entered 'None (0)'	System	13 Sep 2020 23:07:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:07:21', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'f5d92c2c-f6ba-4c4b-83bc-eb83aa2ae80c'	System	13 Sep 2020 23:07:38
User entered 'None (0)'	System	13 Sep 2020 23:07:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:07:23', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'f5d92c2c-f6ba-4c4b-83bc-eb83aa2ae80c'	System	13 Sep 2020 23:07:38
User entered 'None (0)'	System	13 Sep 2020 23:07:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:07:26', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'f5d92c2c-f6ba-4c4b-83bc-eb83aa2ae80c' User entered 'None (0)'	System	13 Sep 2020 23:07:38
	System	13 Sep 2020 23:07:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:07:31', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'f5d92c2c-f6ba-4c4b-83bc-eb83aa2ae80c'	System	13 Sep 2020 23:07:38
User entered 'No (N)'	System	13 Sep 2020 23:07:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-13T19:07:34', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'f5d92c2c-f6ba-4c4b-83bc-eb83aa2ae80c'	System	13 Sep 2020 23:07:38
User entered '13 Sep 2020 19:07'	System	13 Sep 2020 23:07:38

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 6'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:39', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '627bf4a6-ca2c-47fd-acaf-1f3578bb0952'	System	14 Sep 2020 23:03:06
User entered 'None (0)'	System	14 Sep 2020 23:03:06

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:41', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '627bf4a6-ca2c-47fd-acaf-1f3578bb0952'	System	14 Sep 2020 23:03:06
User entered 'None (0)'	System	14 Sep 2020 23:03:06

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:43', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '627bf4a6-ca2c-47fd-acaf-1f3578bb0952'	System	14 Sep 2020 23:03:06
User entered 'None (0)'	System	14 Sep 2020 23:03:06

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:46', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '627bf4a6-ca2c-47fd-acaf-1f3578bb0952'	System	14 Sep 2020 23:03:06
User entered 'None (0)'	System	14 Sep 2020 23:03:06

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:48', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '627bf4a6-ca2c-47fd-acaf-1f3578bb0952'	System	14 Sep 2020 23:03:06
User entered 'None (0)'	System	14 Sep 2020 23:03:06

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:50', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '627bf4a6-ca2c-47fd-acaf-1f3578bb0952'	System	14 Sep 2020 23:03:06
User entered 'None (0)'	System	14 Sep 2020 23:03:06

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:56', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '627bf4a6-ca2c-47fd-acaf-1f3578bb0952'	System	14 Sep 2020 23:03:06
User entered 'No (N)'	System	14 Sep 2020 23:03:06

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-14T19:02:59', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '627bf4a6-ca2c-47fd-acaf-1f3578bb0952'	System	14 Sep 2020 23:03:06
User entered '14 Sep 2020 19:02'	System	14 Sep 2020 23:03:06

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 7'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:51:06', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '20742a26-e76c-4e11-a6cd-5e9291a38752'	System	15 Sep 2020 22:51:50
User entered 'None (0)'	System	15 Sep 2020 22:51:50

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:51:15', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '20742a26-e76c-4e11-a6cd-5e9291a38752'	System	15 Sep 2020 22:51:50
User entered 'None (0)'	System	15 Sep 2020 22:51:50

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:51:18', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '20742a26-e76c-4e11-a6cd-5e9291a38752'	System	15 Sep 2020 22:51:50
User entered 'None (0)'	System	15 Sep 2020 22:51:50

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:51:24', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '20742a26-e76c-4e11-a6cd-5e9291a38752'	System	15 Sep 2020 22:51:50
User entered 'None (0)'	System	15 Sep 2020 22:51:50

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:51:28', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '20742a26-e76c-4e11-a6cd-5e9291a38752'	System	15 Sep 2020 22:51:50
User entered 'None (0)'	System	15 Sep 2020 22:51:50

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:51:31', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '20742a26-e76c-4e11-a6cd-5e9291a38752'	System	15 Sep 2020 22:51:50
User entered 'None (0)'	System	15 Sep 2020 22:51:50

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:51:41', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '20742a26-e76c-4e11-a6cd-5e9291a38752'	System	15 Sep 2020 22:51:50
User entered 'No (N)'	System	15 Sep 2020 22:51:50

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-09-15T18:51:43', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '20742a26-e76c-4e11-a6cd-5e9291a38752'	System	15 Sep 2020 22:51:50
User entered '15 Sep 2020 18:51'	System	15 Sep 2020 22:51:50

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 15:24:01

US3622169

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:46:51
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:04:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 15:44:35

US3622169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:46:51
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:04:46
User entered '16 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 15:44:35

US3622169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:46:51
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:04:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 15:44:35

US3622169

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:46:51
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:04:46
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 15:44:35

US3622169

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:47:05
User signature succeeded.	Susanne Doblecki-Lewis	26 Sep 2020 13:04:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 15:44:40

US3622169

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:34
User entered '1'	System	18 Sep 2020 15:44:40

US3622169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:39:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:47:33
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	29 Sep 2020 12:16:56

US3622169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:39:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:47:33
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '23 Sep 2020'	Junlin Long (b) (4)	29 Sep 2020 12:16:56

US3622169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:39:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:47:33
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	29 Sep 2020 12:16:56

US3622169

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:39:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:47:33
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered empty.	Junlin Long (b) (4)	29 Sep 2020 12:16:56

US3622169

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:39:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:47:44
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	29 Sep 2020 12:17:03

US3622169

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:39:08
User entered '1'	System	29 Sep 2020 12:17:03

US3622169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:48:05
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	05 Oct 2020 17:01:51

US3622169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:48:05
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '30 Sep 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	05 Oct 2020 17:01:51

US3622169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:48:05
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	05 Oct 2020 17:01:51

US3622169

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:48:05
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered empty.	Junlin Long (b) (4)	05 Oct 2020 17:01:51

US3622169

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:48:17
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	05 Oct 2020 17:01:56

US3622169

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:43:56
User entered '1'	System	05 Oct 2020 17:01:56

US3622169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:48:43
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Oct 2020 12:56:19

US3622169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:48:43
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '7 Oct 2020'	Junlin Long (b) (4)	07 Oct 2020 12:56:19

US3622169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:48:43
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	07 Oct 2020 12:56:19

US3622169

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'VISIT2'	System	07 Oct 2020 12:56:19

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User accepted default value 'Pre-Dose (PREDOSE)'	Junlin Long (b) (4)	07 Oct 2020 14:13:11
	(b) (4)	

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '7 Oct 2020'	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '07:35'	(b) (4) Junlin Long (b) (4) (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '7 Oct 2020 07:35'	System	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '98.4' F	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Oral (Oral)'	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered empty.	(b) (4)	
	Junlin Long (b) (4)	07 Oct 2020 14:13:11
	(b) (4)	

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '94'	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'bpm'	System	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '16'	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'breaths/min'	System	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '115'	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'mmHg'	System	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '87'	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:14:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'mmHg'	System	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User accepted default value 'Post-Dose (POSTDOSE)'	Junlin Long (b) (4) (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '7 Oct 2020'	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '09:20'	(b) (4) Junlin Long (b) (4) (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '7 Oct 2020 09:20'	System	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '98.4' F	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Oral (Oral)'	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered empty.	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '85'	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'bpm'	System	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '20'	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'breaths/min'	System	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '113'	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'mmHg'	System	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:28
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '85'	Junlin Long (b) (4)	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:14:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'mmHg'	System	07 Oct 2020 14:13:11

US3622169

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:05
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Oct 2020 14:13:18

US3622169

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:49:05
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '7 Oct 2020'	Junlin Long (b) (4)	07 Oct 2020 14:13:18

US3622169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:48:53
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Oct 2020 12:56:41

US3622169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:48:53
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered empty.	Junlin Long (b) (4)	07 Oct 2020 12:56:41

US3622169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

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)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:48:53
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered empty.	Junlin Long (b) (4)	07 Oct 2020 12:56:41

US3622169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 12:56:41

US3622169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:48:53
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '7 Oct 2020'	Junlin Long (b) (4)	07 Oct 2020 12:56:41

US3622169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:48:53
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '08:47'	Junlin Long (b) (4)	07 Oct 2020 12:56:41

US3622169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '7 Oct 2020 08:47'	System	07 Oct 2020 12:56:41

US3622169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:48:53
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Left Arm (LEFT ARM)'	Junlin Long (b) (4)	07 Oct 2020 12:56:41

US3622169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:48:53
User entered 'ONCE'	System	07 Oct 2020 12:56:41

US3622169

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 12:56:41

US3622169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:50:03
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Oct 2020 14:13:35

US3622169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 09:58:10
	(b) (4), (b) (6)	12 Nov 2020 11:50:03
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Sample is for V2/Day29. Data changed submitted to Preclarus. Per sponsor instructions, unscheduled kit was used due to sponsor kit inventory issues. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:51:53
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:32:55
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '7 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	07 Oct 2020 14:13:35

US3622169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:50:03
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '07:40'	(b) (4) Junlin Long (b) (4) (b) (4)	07 Oct 2020 14:13:35

US3622169

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '7 Oct 2020 07:40'	System	07 Oct 2020 14:13:35

US3622169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:14:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:50:14
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 07Oct2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 01:29:00
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 07Oct2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'Sample is for V2/Day29. Data changed submitted to Preclarus. Per sponsor instructions, unscheduled kit was used due to sponsor kit inventory issues.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:56:15
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 07Oct2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:49:43
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '7 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	07 Oct 2020 14:13:48

US3622169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Junlin Long (b) (4) (b) (4)	07 Oct 2020 14:13:48

US3622169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:50:14
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Oct 2020 14:13:48

US3622169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:50:14
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered '07:47'	(b) (4) Junlin Long (b) (4) (b) (4)	07 Oct 2020 14:13:48

US3622169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '7 Oct 2020 07:47'	System	07 Oct 2020 14:13:48

US3622169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:19

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Junlin Long (b) (4) (b) (4)	07 Oct 2020 14:13:48

US3622169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:50:14
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'No (N)'	Junlin Long (b) (4)	07 Oct 2020 14:13:48

US3622169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:50:14
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered empty.	Junlin Long (b) (4)	07 Oct 2020 14:13:48

US3622169

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered empty.	System	07 Oct 2020 14:13:48

US3622169

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:50:27
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Oct 2020 14:13:54

US3622169

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:16:47
User entered '1'	System	07 Oct 2020 14:13:54

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:22:18', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ca7f83dc-a69f-4860-a3c0-7ecf091966b3'	System	07 Oct 2020 13:22:45
User entered 'Yes (Y)'	System	07 Oct 2020 13:22:45

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:22:26', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ca7f83dc-a69f-4860-a3c0-7ecf091966b3'	System	07 Oct 2020 13:22:45
User entered '98.4'	System	07 Oct 2020 13:22:45

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:22:35', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ca7f83dc-a69f-4860-a3c0-7ecf091966b3'	System	07 Oct 2020 13:22:45
User entered 'No (N)'	System	07 Oct 2020 13:22:45

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:22:41', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ca7f83dc-a69f-4860-a3c0-7ecf091966b3'	System	07 Oct 2020 13:22:45
User entered '07 Oct 2020 09:22'	System	07 Oct 2020 13:22:45

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '07 Oct 2020 09:07'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '07 Oct 2020 11:37'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:02', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'de8937ae-d0d4-4d31-8cb8-f45bd8316a04'	System	07 Oct 2020 22:58:19
User entered 'Yes (Y)'	System	07 Oct 2020 22:58:19

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:08', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'de8937ae-d0d4-4d31-8cb8-f45bd8316a04'	System	07 Oct 2020 22:58:19
User entered '98.3'	System	07 Oct 2020 22:58:19

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:12', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'de8937ae-d0d4-4d31-8cb8-f45bd8316a04'	System	07 Oct 2020 22:58:19
User entered 'No (N)'	System	07 Oct 2020 22:58:19

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:15', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'de8937ae-d0d4-4d31-8cb8-f45bd8316a04'	System	07 Oct 2020 22:58:19
User entered '07 Oct 2020 18:58'	System	07 Oct 2020 22:58:19

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '07 Oct 2020 12:32'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 2'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:04:55', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '317d57b1-8bf3-4488-a9d4-cdd9adc4caa3'	System	09 Oct 2020 02:05:15
User entered 'Yes (Y)'	System	09 Oct 2020 02:05:15

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:03', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '317d57b1-8bf3-4488-a9d4-cdd9adc4caa3'	System	09 Oct 2020 02:05:15
User entered '98.4'	System	09 Oct 2020 02:05:15

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:07', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '317d57b1-8bf3-4488-a9d4-cdd9adc4caa3'	System	09 Oct 2020 02:05:15
User entered 'No (N)'	System	09 Oct 2020 02:05:15

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:10', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '317d57b1-8bf3-4488-a9d4-cdd9adc4caa3'	System	09 Oct 2020 02:05:15
User entered '08 Oct 2020 22:05'	System	09 Oct 2020 02:05:15

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 3'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:25:19', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'd42a5d3b-b631-4acc-8d69-46eff059d9b0'	System	09 Oct 2020 22:25:36
User entered 'Yes (Y)'	System	09 Oct 2020 22:25:36

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:25:25', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'd42a5d3b-b631-4acc-8d69-46eff059d9b0'	System	09 Oct 2020 22:25:36
User entered '98.3'	System	09 Oct 2020 22:25:36

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:25:29', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'd42a5d3b-b631-4acc-8d69-46eff059d9b0'	System	09 Oct 2020 22:25:36
User entered 'No (N)'	System	09 Oct 2020 22:25:36

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:25:32', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'd42a5d3b-b631-4acc-8d69-46eff059d9b0'	System	09 Oct 2020 22:25:36
User entered '09 Oct 2020 18:25'	System	09 Oct 2020 22:25:36

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 4'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:27:25', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5b935baf-b60a-4f5d-a523-a4d2c596194d'	System	10 Oct 2020 20:27:44
User entered 'Yes (Y)'	System	10 Oct 2020 20:27:44

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:27:31', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5b935baf-b60a-4f5d-a523-a4d2c596194d'	System	10 Oct 2020 20:27:44
User entered '98.5'	System	10 Oct 2020 20:27:44

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:27:36', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5b935baf-b60a-4f5d-a523-a4d2c596194d'	System	10 Oct 2020 20:27:44
User entered 'No (N)'	System	10 Oct 2020 20:27:44

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:27:38', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5b935baf-b60a-4f5d-a523-a4d2c596194d'	System	10 Oct 2020 20:27:44
User entered '10 Oct 2020 16:27'	System	10 Oct 2020 20:27:44

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 5'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 6'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:01:24', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '3fcd5b98-02b7-4d6c-a43c-58e0ee3b3357'	System	12 Oct 2020 21:01:42
User entered 'Yes (Y)'	System	12 Oct 2020 21:01:42

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:01:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '3fcd5b98-02b7-4d6c-a43c-58e0ee3b3357'	System	12 Oct 2020 21:01:42
User entered '98.2'	System	12 Oct 2020 21:01:42

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:01:35', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '3fcd5b98-02b7-4d6c-a43c-58e0ee3b3357'	System	12 Oct 2020 21:01:42
User entered 'No (N)'	System	12 Oct 2020 21:01:42

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:01:38', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '3fcd5b98-02b7-4d6c-a43c-58e0ee3b3357'	System	12 Oct 2020 21:01:42
User entered '12 Oct 2020 17:01'	System	12 Oct 2020 21:01:42

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 7'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:00', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ccd680d5-4cdf-47a3-a55f-064d369c3577'	System	13 Oct 2020 19:17:19
User entered 'Yes (Y)'	System	13 Oct 2020 19:17:19

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:06', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ccd680d5-4cdf-47a3-a55f-064d369c3577'	System	13 Oct 2020 19:17:19
User entered '98.5'	System	13 Oct 2020 19:17:19

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:11', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ccd680d5-4cdf-47a3-a55f-064d369c3577'	System	13 Oct 2020 19:17:19
User entered 'No (N)'	System	13 Oct 2020 19:17:19

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:13', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ccd680d5-4cdf-47a3-a55f-064d369c3577'	System	13 Oct 2020 19:17:19
User entered '13 Oct 2020 15:17'	System	13 Oct 2020 19:17:19

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:22:47', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '6fcbc85e-ff05-452d-88c4-ba5409e90dd3'	System	07 Oct 2020 13:23:07
User entered 'None (1)'	System	07 Oct 2020 13:23:07

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:22:51', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '6fcbc85e-ff05-452d-88c4-ba5409e90dd3'	System	07 Oct 2020 13:23:07
User entered 'No (N)'	System	07 Oct 2020 13:23:07

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:22:54', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '6fcbc85e-ff05-452d-88c4-ba5409e90dd3'	System	07 Oct 2020 13:23:07
User entered 'No (N)'	System	07 Oct 2020 13:23:07

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:22:58', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '6fc85e-ff05-452d-88c4-ba5409e90dd3'	System	07 Oct 2020 13:23:07
User entered 'None (1)'	System	07 Oct 2020 13:23:07

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:23:01', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '6fcbc85e-ff05-452d-88c4-ba5409e90dd3'	System	07 Oct 2020 13:23:07
User entered '07 Oct 2020 09:23'	System	07 Oct 2020 13:23:07

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '07 Oct 2020 09:07'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '07 Oct 2020 11:37'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:20', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '69ac3652-129c-4e2f-b15c-85058855983d'	System	07 Oct 2020 22:58:38
User entered 'None (1)'	System	07 Oct 2020 22:58:38

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:24', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '69ac3652-129c-4e2f-b15c-85058855983d'	System	07 Oct 2020 22:58:38
User entered 'No (N)'	System	07 Oct 2020 22:58:38

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:27', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '69ac3652-129c-4e2f-b15c-85058855983d'	System	07 Oct 2020 22:58:38
User entered 'No (N)'	System	07 Oct 2020 22:58:38

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:32', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '69ac3652-129c-4e2f-b15c-85058855983d'	System	07 Oct 2020 22:58:38
User entered 'None (1)'	System	07 Oct 2020 22:58:38

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:34', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '69ac3652-129c-4e2f-b15c-85058855983d' User entered '07 Oct 2020 18:58'	System	07 Oct 2020 22:58:38
	System	07 Oct 2020 22:58:38

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '07 Oct 2020 12:32'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 2'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:15', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5a2e01d0-02e2-4514-a329-20b5f40046a7'	System	09 Oct 2020 02:05:36
User entered 'None (1)'	System	09 Oct 2020 02:05:36

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:20', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5a2e01d0-02e2-4514-a329-20b5f40046a7'	System	09 Oct 2020 02:05:36
User entered 'No (N)'	System	09 Oct 2020 02:05:36

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:23', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5a2e01d0-02e2-4514-a329-20b5f40046a7'	System	09 Oct 2020 02:05:36
User entered 'No (N)'	System	09 Oct 2020 02:05:36

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:28', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5a2e01d0-02e2-4514-a329-20b5f40046a7'	System	09 Oct 2020 02:05:36
User entered 'None (1)'	System	09 Oct 2020 02:05:36

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5a2e01d0-02e2-4514-a329-20b5f40046a7'	System	09 Oct 2020 02:05:36
User entered '08 Oct 2020 22:05'	System	09 Oct 2020 02:05:36

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 3'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:25:40', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'bb325ff3-c340-4ee1-a988-c6779d9562ec'	System	09 Oct 2020 22:26:00
User entered 'None (1)'	System	09 Oct 2020 22:26:00

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:25:45', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'bb325ff3-c340-4ee1-a988-c6779d9562ec'	System	09 Oct 2020 22:26:00
User entered 'No (N)'	System	09 Oct 2020 22:26:00

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:25:49', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'bb325ff3-c340-4ee1-a988-c6779d9562ec'	System	09 Oct 2020 22:26:00
User entered 'No (N)'	System	09 Oct 2020 22:26:00

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:25:52', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'bb325ff3-c340-4ee1-a988-c6779d9562ec'	System	09 Oct 2020 22:26:00
User entered 'None (1)'	System	09 Oct 2020 22:26:00

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:25:55', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'bb325ff3-c340-4ee1-a988-c6779d9562ec'	System	09 Oct 2020 22:26:00
User entered '09 Oct 2020 18:25'	System	09 Oct 2020 22:26:00

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 4'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:27:46', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '856ddb49-7648-49b5-9d50-92392cfa79a4'	System	10 Oct 2020 20:28:03
User entered 'None (1)'	System	10 Oct 2020 20:28:03

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:27:49', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '856ddb49-7648-49b5-9d50-92392cfa79a4'	System	10 Oct 2020 20:28:03
User entered 'No (N)'	System	10 Oct 2020 20:28:03

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:27:52', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '856ddb49-7648-49b5-9d50-92392cfa79a4'	System	10 Oct 2020 20:28:03
User entered 'No (N)'	System	10 Oct 2020 20:28:03

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:27:56', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '856ddb49-7648-49b5-9d50-92392cfa79a4'	System	10 Oct 2020 20:28:03
User entered 'None (1)'	System	10 Oct 2020 20:28:03

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:27:59', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '856ddb49-7648-49b5-9d50-92392cfa79a4'	System	10 Oct 2020 20:28:03
User entered '10 Oct 2020 16:27'	System	10 Oct 2020 20:28:03

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 5'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 6'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:01:44', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ec3f6d84-162f-4690-9bee-48ed1ac41037'	System	12 Oct 2020 21:02:00
User entered 'None (1)'	System	12 Oct 2020 21:02:00

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:01:48', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ec3f6d84-162f-4690-9bee-48ed1ac41037'	System	12 Oct 2020 21:02:00
User entered 'No (N)'	System	12 Oct 2020 21:02:00

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:01:51', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ec3f6d84-162f-4690-9bee-48ed1ac41037'	System	12 Oct 2020 21:02:00
User entered 'No (N)'	System	12 Oct 2020 21:02:00

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:01:55', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ec3f6d84-162f-4690-9bee-48ed1ac41037'	System	12 Oct 2020 21:02:00
User entered 'None (1)'	System	12 Oct 2020 21:02:00

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:01:57', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'ec3f6d84-162f-4690-9bee-48ed1ac41037'	System	12 Oct 2020 21:02:00
User entered '12 Oct 2020 17:01'	System	12 Oct 2020 21:02:00

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 7'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:19', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '43e907d0-c3ef-4c4d-a201-62f8b856f90a'	System	13 Oct 2020 19:17:39
User entered 'None (1)'	System	13 Oct 2020 19:17:39

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:22', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '43e907d0-c3ef-4c4d-a201-62f8b856f90a'	System	13 Oct 2020 19:17:39
User entered 'No (N)'	System	13 Oct 2020 19:17:39

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:26', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '43e907d0-c3ef-4c4d-a201-62f8b856f90a'	System	13 Oct 2020 19:17:39
User entered 'No (N)'	System	13 Oct 2020 19:17:39

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:29', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '43e907d0-c3ef-4c4d-a201-62f8b856f90a'	System	13 Oct 2020 19:17:39
User entered 'None (1)'	System	13 Oct 2020 19:17:39

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:32', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '43e907d0-c3ef-4c4d-a201-62f8b856f90a'	System	13 Oct 2020 19:17:39
User entered '13 Oct 2020 15:17'	System	13 Oct 2020 19:17:39

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:23:06', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'e08f7029-b067-4d64-a41d-20354287fa5b'	System	07 Oct 2020 13:23:44
User entered 'None (0)'	System	07 Oct 2020 13:23:44

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:23:10', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'e08f7029-b067-4d64-a41d-20354287fa5b'	System	07 Oct 2020 13:23:44
User entered 'None (0)'	System	07 Oct 2020 13:23:44

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:23:13', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'e08f7029-b067-4d64-a41d-20354287fa5b'	System	07 Oct 2020 13:23:44
User entered 'None (0)'	System	07 Oct 2020 13:23:44

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:23:21', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'e08f7029-b067-4d64-a41d-20354287fa5b'	System	07 Oct 2020 13:23:44
User entered 'None (0)'	System	07 Oct 2020 13:23:44

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:23:24', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'e08f7029-b067-4d64-a41d-20354287fa5b'	System	07 Oct 2020 13:23:44
User entered 'None (0)'	System	07 Oct 2020 13:23:44

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:23:31', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'e08f7029-b067-4d64-a41d-20354287fa5b'	System	07 Oct 2020 13:23:44
User entered 'None (0)'	System	07 Oct 2020 13:23:44

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:23:36', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'e08f7029-b067-4d64-a41d-20354287fa5b'	System	07 Oct 2020 13:23:44
User entered 'No (N)'	System	07 Oct 2020 13:23:44

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T09:23:38', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'e08f7029-b067-4d64-a41d-20354287fa5b'	System	07 Oct 2020 13:23:44
User entered '07 Oct 2020 09:23'	System	07 Oct 2020 13:23:44

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '07 Oct 2020 09:07'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '07 Oct 2020 11:37'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:39', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '87389438-8928-4ddc-8e39-df58d66d22c3'	System	07 Oct 2020 22:59:05
User entered 'None (0)'	System	07 Oct 2020 22:59:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:42', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '87389438-8928-4ddc-8e39-df58d66d22c3'	System	07 Oct 2020 22:59:05
User entered 'None (0)'	System	07 Oct 2020 22:59:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:45', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '87389438-8928-4ddc-8e39-df58d66d22c3'	System	07 Oct 2020 22:59:05
User entered 'None (0)'	System	07 Oct 2020 22:59:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:48', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '87389438-8928-4ddc-8e39-df58d66d22c3'	System	07 Oct 2020 22:59:05
User entered 'None (0)'	System	07 Oct 2020 22:59:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:51', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '87389438-8928-4ddc-8e39-df58d66d22c3'	System	07 Oct 2020 22:59:05
User entered 'None (0)'	System	07 Oct 2020 22:59:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:54', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '87389438-8928-4ddc-8e39-df58d66d22c3'	System	07 Oct 2020 22:59:05
User entered 'None (0)'	System	07 Oct 2020 22:59:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:58:58', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '87389438-8928-4ddc-8e39-df58d66d22c3'	System	07 Oct 2020 22:59:05
User entered 'No (N)'	System	07 Oct 2020 22:59:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-07T18:59:00', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '87389438-8928-4ddc-8e39-df58d66d22c3'	System	07 Oct 2020 22:59:05
User entered '07 Oct 2020 18:59'	System	07 Oct 2020 22:59:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '07 Oct 2020 12:32'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 2'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:35', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '33bbe1cd-bfa2-4220-991d-6238779a1fba'	System	09 Oct 2020 02:06:06
User entered 'None (0)'	System	09 Oct 2020 02:06:06

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:37', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '33bbe1cd-bfa2-4220-991d-6238779a1fba'	System	09 Oct 2020 02:06:06
User entered 'None (0)'	System	09 Oct 2020 02:06:06

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:40', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '33bbe1cd-bfa2-4220-991d-6238779a1fba'	System	09 Oct 2020 02:06:06
User entered 'None (0)'	System	09 Oct 2020 02:06:06

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:42', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '33bbe1cd-bfa2-4220-991d-6238779a1fba'	System	09 Oct 2020 02:06:06
User entered 'None (0)'	System	09 Oct 2020 02:06:06

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:45', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '33bbe1cd-bfa2-4220-991d-6238779a1fba'	System	09 Oct 2020 02:06:06
User entered 'None (0)'	System	09 Oct 2020 02:06:06

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:47', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '33bbe1cd-bfa2-4220-991d-6238779a1fba'	System	09 Oct 2020 02:06:06
User entered 'None (0)'	System	09 Oct 2020 02:06:06

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:54', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '33bbe1cd-bfa2-4220-991d-6238779a1fba'	System	09 Oct 2020 02:06:06
User entered 'No (N)'	System	09 Oct 2020 02:06:06

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-08T22:05:57', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '33bbe1cd-bfa2-4220-991d-6238779a1fba'	System	09 Oct 2020 02:06:06
User entered '08 Oct 2020 22:05'	System	09 Oct 2020 02:06:06

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 3'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:26:02', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '24d2bd04-022c-44da-aa6e-3b044c6d7649'	System	09 Oct 2020 22:26:31
User entered 'None (0)'	System	09 Oct 2020 22:26:31

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:26:04', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '24d2bd04-022c-44da-aa6e-3b044c6d7649'	System	09 Oct 2020 22:26:31
User entered 'None (0)'	System	09 Oct 2020 22:26:31

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:26:06', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '24d2bd04-022c-44da-aa6e-3b044c6d7649'	System	09 Oct 2020 22:26:31
User entered 'None (0)'	System	09 Oct 2020 22:26:31

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:26:08', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '24d2bd04-022c-44da-aa6e-3b044c6d7649'	System	09 Oct 2020 22:26:31
User entered 'None (0)'	System	09 Oct 2020 22:26:31

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:26:11', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '24d2bd04-022c-44da-aa6e-3b044c6d7649'	System	09 Oct 2020 22:26:31
User entered 'None (0)'	System	09 Oct 2020 22:26:31

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:26:13', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '24d2bd04-022c-44da-aa6e-3b044c6d7649'	System	09 Oct 2020 22:26:31
User entered 'None (0)'	System	09 Oct 2020 22:26:31

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:26:24', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '24d2bd04-022c-44da-aa6e-3b044c6d7649'	System	09 Oct 2020 22:26:31
User entered 'No (N)'	System	09 Oct 2020 22:26:31

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-09T18:26:26', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '24d2bd04-022c-44da-aa6e-3b044c6d7649' User entered '09 Oct 2020 18:26'	System	09 Oct 2020 22:26:31
	System	09 Oct 2020 22:26:31

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 4'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:28:03', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0deee58e-1fb7-447a-8d3d-daf4fb7daba5'	System	10 Oct 2020 20:28:36
User entered 'None (0)'	System	10 Oct 2020 20:28:36

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:28:05', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0deee58e-1fb7-447a-8d3d-daf4fb7daba5'	System	10 Oct 2020 20:28:36
User entered 'None (0)'	System	10 Oct 2020 20:28:36

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:28:07', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0deee58e-1fb7-447a-8d3d-daf4fb7daba5'	System	10 Oct 2020 20:28:36
User entered 'None (0)'	System	10 Oct 2020 20:28:36

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:28:08', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0deee58e-1fb7-447a-8d3d-daf4fb7daba5'	System	10 Oct 2020 20:28:36
User entered 'None (0)'	System	10 Oct 2020 20:28:36

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:28:10', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0deee58e-1fb7-447a-8d3d-daf4fb7daba5'	System	10 Oct 2020 20:28:36
User entered 'None (0)'	System	10 Oct 2020 20:28:36

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:28:12', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0deee58e-1fb7-447a-8d3d-daf4fb7daba5'	System	10 Oct 2020 20:28:36
User entered 'None (0)'	System	10 Oct 2020 20:28:36

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:28:21', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0deee58e-1fb7-447a-8d3d-daf4fb7daba5'	System	10 Oct 2020 20:28:36
User entered 'No (N)'	System	10 Oct 2020 20:28:36

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-10T16:28:29', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '0deee58e-1fb7-447a-8d3d-daf4fb7daba5'	System	10 Oct 2020 20:28:36
User entered '10 Oct 2020 16:28'	System	10 Oct 2020 20:28:36

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 5'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 6'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:02:04', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'b8dcb60c-e674-4d67-b79c-d76238fad840'	System	12 Oct 2020 21:02:30
User entered 'None (0)'	System	12 Oct 2020 21:02:30

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:02:06', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'b8dcb60c-e674-4d67-b79c-d76238fad840'	System	12 Oct 2020 21:02:30
User entered 'None (0)'	System	12 Oct 2020 21:02:30

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:02:09', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'b8dcb60c-e674-4d67-b79c-d76238fad840'	System	12 Oct 2020 21:02:30
User entered 'None (0)'	System	12 Oct 2020 21:02:30

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:02:13', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'b8dcb60c-e674-4d67-b79c-d76238fad840'	System	12 Oct 2020 21:02:30
User entered 'None (0)'	System	12 Oct 2020 21:02:30

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:02:16', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'b8dcb60c-e674-4d67-b79c-d76238fad840'	System	12 Oct 2020 21:02:30
User entered 'None (0)'	System	12 Oct 2020 21:02:30

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:02:19', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'b8dcb60c-e674-4d67-b79c-d76238fad840'	System	12 Oct 2020 21:02:30
User entered 'None (0)'	System	12 Oct 2020 21:02:30

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:02:23', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'b8dcb60c-e674-4d67-b79c-d76238fad840'	System	12 Oct 2020 21:02:30
User entered 'No (N)'	System	12 Oct 2020 21:02:30

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-12T17:02:26', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'b8dcb60c-e674-4d67-b79c-d76238fad840'	System	12 Oct 2020 21:02:30
User entered '12 Oct 2020 17:02'	System	12 Oct 2020 21:02:30

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	07 Oct 2020 12:56:41
User entered 'Day 7'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:40', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c5b995d8-e6e0-4564-84be-ffa7c81c0f3e'	System	13 Oct 2020 19:18:05
User entered 'None (0)'	System	13 Oct 2020 19:18:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:42', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c5b995d8-e6e0-4564-84be-ffa7c81c0f3e'	System	13 Oct 2020 19:18:05
User entered 'None (0)'	System	13 Oct 2020 19:18:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:44', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c5b995d8-e6e0-4564-84be-ffa7c81c0f3e' User entered 'None (0)'	System	13 Oct 2020 19:18:05
	System	13 Oct 2020 19:18:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:46', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c5b995d8-e6e0-4564-84be-ffa7c81c0f3e'	System	13 Oct 2020 19:18:05
User entered 'None (0)'	System	13 Oct 2020 19:18:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:48', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c5b995d8-e6e0-4564-84be-ffa7c81c0f3e'	System	13 Oct 2020 19:18:05
User entered 'None (0)'	System	13 Oct 2020 19:18:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:50', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c5b995d8-e6e0-4564-84be-ffa7c81c0f3e'	System	13 Oct 2020 19:18:05
User entered 'None (0)'	System	13 Oct 2020 19:18:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:53', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c5b995d8-e6e0-4564-84be-ffa7c81c0f3e'	System	13 Oct 2020 19:18:05
User entered 'No (N)'	System	13 Oct 2020 19:18:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ada1a9f61375bac5)', Time: '2020-10-13T15:17:58', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: 'c5b995d8-e6e0-4564-84be-ffa7c81c0f3e' User entered '13 Oct 2020 15:17'	System	13 Oct 2020 19:18:05
	System	13 Oct 2020 19:18:05

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 12:56:41

US3622169

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:14:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 12:56:41

US3622169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:07:01
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:50:58
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:03:59
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 15:24:22

US3622169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:07:01
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:50:58
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:03:59
User entered '15 Oct 2020'	Junlin Long (b) (4)	15 Oct 2020 15:24:22

US3622169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:07:01
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:50:58
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:03:59
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	15 Oct 2020 15:24:22

US3622169

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:07:01
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:50:58
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:03:59
User entered empty.	Junlin Long (b) (4)	15 Oct 2020 15:24:22

US3622169

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:07:01
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:51:10
User signature succeeded.	Susanne Doblecki-Lewis	15 Oct 2020 20:03:59
User entered 'Yes (Y)'	Junlin Long (b) (4)	15 Oct 2020 15:24:26

US3622169

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:07:01
User entered '1'	System	15 Oct 2020 15:24:26

US3622169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:51:37
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:58:40
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 19:06:24

US3622169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:51:37
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:58:40
User entered '21 Oct 2020'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 19:06:24

US3622169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:51:37
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:58:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Junlin Long (b) (4) (b) (4)	21 Oct 2020 19:06:24

US3622169

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:51:37
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:58:40
User entered empty.	Junlin Long (b) (4)	21 Oct 2020 19:06:24

US3622169

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:51:46
User signature succeeded.	Susanne Doblecki-Lewis	24 Oct 2020 14:58:40
User entered 'Yes (Y)'	Junlin Long (b) (4)	21 Oct 2020 19:06:28

US3622169

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:06
User entered '1'	System	21 Oct 2020 19:06:28

US3622169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:04
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered 'Yes (Y)'	Junlin Long	28 Oct 2020 16:16:02

US3622169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:04
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered '28 Oct 2020'	Junlin Long	28 Oct 2020 16:16:02

US3622169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:04
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered 'Contact Made (CONTACT MADE)'	Junlin Long	28 Oct 2020 16:16:02

US3622169

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:04
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
	(b) (4)	
User entered empty.	Junlin Long (b) (4)	28 Oct 2020 16:16:02
	(b) (4)	

US3622169

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:15
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered 'Yes (Y)'	Junlin Long	28 Oct 2020 16:16:28

US3622169

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:53:07
User entered '1'	System	28 Oct 2020 16:16:28

US3622169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:41
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered 'Yes (Y)'	Junlin Long (b) (4)	04 Nov 2020 14:25:57

US3622169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:41
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered '4 Nov 2020'	Junlin Long (b) (4)	04 Nov 2020 14:25:57

US3622169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

[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 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:41
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered 'Clinic (Clinic)'	Junlin Long (b) (4)	04 Nov 2020 14:25:57

US3622169

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:14:19

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
User entered 'VISIT3'	System	04 Nov 2020 14:25:57

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:51
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered 'Yes (Y)'	Junlin Long (b) (4)	04 Nov 2020 14:26:23

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:51
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered '4 Nov 2020'	Junlin Long (b) (4)	04 Nov 2020 14:26:23

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:51
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered '07:19'	Junlin Long (b) (4)	04 Nov 2020 14:26:23

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
User entered '4 Nov 2020 07:19'	System	04 Nov 2020 14:26:23

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:51
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered '98.3' F	Junlin Long (b) (4)	04 Nov 2020 14:26:23

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:51
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered 'Oral (Oral)'	Junlin Long (b) (4)	04 Nov 2020 14:26:23

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:51
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered empty.	Junlin Long (b) (4)	04 Nov 2020 14:26:23

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:51
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered '72'	Junlin Long (b) (4)	04 Nov 2020 14:26:23

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
User entered 'bpm'	System	04 Nov 2020 14:26:23

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:51
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered '16'	Junlin Long (b) (4)	04 Nov 2020 14:26:23

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
User entered 'breaths/min'	System	04 Nov 2020 14:26:23

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:51
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered '90'	Junlin Long (b) (4)	04 Nov 2020 14:26:23

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
User entered 'mmHg'	System	04 Nov 2020 14:26:23

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:52:51
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered '70'	Junlin Long (b) (4)	04 Nov 2020 14:26:23

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
User entered 'mmHg'	System	04 Nov 2020 14:26:23

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34

US3622169

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:14:19

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34

US3622169

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:53:21
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered 'No (N)'	Junlin Long (b) (4)	04 Nov 2020 14:26:31

US3622169

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:14:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:53:21
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered empty.	Junlin Long (b) (4)	04 Nov 2020 14:26:31

US3622169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:53:34
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered 'Yes (Y)'	Junlin Long (b) (4)	04 Nov 2020 14:26:54

US3622169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:53:34
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered '4 Nov 2020'	Junlin Long (b) (4)	04 Nov 2020 14:26:54

US3622169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:53:34
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered '07:35'	Junlin Long (b) (4)	04 Nov 2020 14:26:54

US3622169

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
User entered '4 Nov 2020 07:35'	System	04 Nov 2020 14:26:54

US3622169

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 11:53:43
User signature succeeded.	Susanne Doblecki-Lewis	10 Nov 2020 16:31:17
User entered 'Yes (Y)'	Junlin Long (b) (4)	04 Nov 2020 14:26:57

US3622169

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:34
User entered '1'	System	04 Nov 2020 14:26:57

US3622169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 64'	System	09 Sep 2020 15:24:01

US3622169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-11-10T19:22:54', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '59aaf3b8-cc2a-4a4d-8f83-efa97bf23144'	System	11 Nov 2020 00:23:16
User entered 'No (N)'	System	11 Nov 2020 00:23:16

US3622169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-11-10T19:23:00', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '59aaf3b8-cc2a-4a4d-8f83-efa97bf23144'	System	11 Nov 2020 00:23:16
User entered 'No (N)'	System	11 Nov 2020 00:23:16

US3622169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-11-10T19:23:09', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '59aaf3b8-cc2a-4a4d-8f83-efa97bf23144'	System	11 Nov 2020 00:23:16
User entered '10 Nov 2020 19:23:09'	System	11 Nov 2020 00:23:16

US3622169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered '09 Nov 2020 00:01'	System	09 Sep 2020 15:24:01

US3622169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered '13 Nov 2020 23:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered 'Day 71'	System	09 Sep 2020 15:24:01

US3622169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-11-16T21:38:57', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5f4cd626-26f5-4900-8671-74349ce81b8f'	System	17 Nov 2020 02:39:12
User entered 'No (N)'	System	17 Nov 2020 02:39:12

US3622169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-11-16T21:39:01', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5f4cd626-26f5-4900-8671-74349ce81b8f'	System	17 Nov 2020 02:39:12
User entered 'No (N)'	System	17 Nov 2020 02:39:12

US3622169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-11-16T21:39:06', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '5f4cd626-26f5-4900-8671-74349ce81b8f'	System	17 Nov 2020 02:39:12
User entered '16 Nov 2020 21:39:06'	System	17 Nov 2020 02:39:12

US3622169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered '16 Nov 2020 00:01'	System	09 Sep 2020 15:24:01

US3622169

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:18:55
Data entry locked.	System	09 Sep 2020 15:24:01
User entered '20 Nov 2020 23:59'	System	09 Sep 2020 15:24:01

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-11-28T11:02:20', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '681ebbf8-801f-46fa-a38d-4bb316c011fa'	System	28 Nov 2020 16:02:39
User entered 'No (N)'	System	28 Nov 2020 16:02:39

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-11-28T11:02:26', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '681ebbf8-801f-46fa-a38d-4bb316c011fa'	System	28 Nov 2020 16:02:39
User entered 'No (N)'	System	28 Nov 2020 16:02:39

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-11-28T11:02:36', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '681ebbf8-801f-46fa-a38d-4bb316c011fa' User entered '28 Nov 2020 11:02:36'	System	28 Nov 2020 16:02:39

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:32:37', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered 'Yes (Y)'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:32:47', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered 'Yes (Y)'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:32:52', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:07', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered 'Yes (Y)'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '0'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '1'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '1'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '0'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '0'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '0'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '0'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '0'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '0'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '0'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '0'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '0'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '0'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '0'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '0'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '0'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:30', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '0'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:38', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:47', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered 'No (N)'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-05T23:33:53', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '90d25ca1-5c8e-4756-9c61-2a802f71202d'	System	06 Dec 2020 04:34:05
User entered '05 Dec 2020 23:33:53'	System	06 Dec 2020 04:34:05

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-11T14:23:48', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '441c805b-fc27-4f6c-9d67-15fc90e5a426'	System	11 Dec 2020 19:24:01
User entered 'No (N)'	System	11 Dec 2020 19:24:01

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-11T14:23:54', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '441c805b-fc27-4f6c-9d67-15fc90e5a426'	System	11 Dec 2020 19:24:01
User entered 'No (N)'	System	11 Dec 2020 19:24:01

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2020-12-11T14:23:57', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '441c805b-fc27-4f6c-9d67-15fc90e5a426'	System	11 Dec 2020 19:24:01
User entered '11 Dec 2020 14:23:57'	System	11 Dec 2020 19:24:01

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2021-01-03T18:30:50', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '868b37d5-bb45-4845-9107-0c6e3601eb64'	System	03 Jan 2021 23:31:02
User entered 'No (N)'	System	03 Jan 2021 23:31:02

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2021-01-03T18:30:56', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '868b37d5-bb45-4845-9107-0c6e3601eb64'	System	03 Jan 2021 23:31:02
User entered 'No (N)'	System	03 Jan 2021 23:31:02

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2021-01-03T18:31:00', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '868b37d5-bb45-4845-9107-0c6e3601eb64'	System	03 Jan 2021 23:31:02
User entered '03 Jan 2021 18:31:00'	System	03 Jan 2021 23:31:02

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2021-01-11T23:15:22', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '1efacecd-3750-490d-9375-093061267f91'	System	12 Jan 2021 04:15:29
User entered 'No (N)'	System	12 Jan 2021 04:15:29

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2021-01-11T23:15:02', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '1efacecd-3750-490d-9375-093061267f91'	System	12 Jan 2021 04:15:29
User entered 'No (N)'	System	12 Jan 2021 04:15:29

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (de09c0444b97c908)', Time: '2021-01-11T23:15:25', User OID: 'PatientReportedOutcome (US3622169)', ODM File OID: '1efacecd-3750-490d-9375-093061267f91'	System	12 Jan 2021 04:15:29
User entered '11 Jan 2021 23:15:25'	System	12 Jan 2021 04:15:29

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 06:32:30

US3622169

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:14:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:32:30
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 06:32:30

US3622169

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:21
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:18:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'Yes (Y)'	Junlin Long (b) (4)	05 Jan 2021 16:09:21

US3622169

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:21
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:18:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered '3 Dec 2020'	Junlin Long (b) (4)	05 Jan 2021 16:09:21

US3622169

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:21
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:18:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	05 Jan 2021 16:09:21

US3622169

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:21
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:18:49
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered empty.	(b) (4) Junlin Long (b) (4) (b) (4)	05 Jan 2021 16:09:21

US3622169

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:21
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:19:00
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'Yes (Y)'	Junlin Long (b) (4)	05 Jan 2021 16:09:26

US3622169

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:18:21
User entered '1'	System	05 Jan 2021 16:09:26

US3622169

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:19:12
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	05 Jan 2021 16:09:37

US3622169

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:19:12
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered '4 Jan 2021'	Junlin Long (b) (4)	05 Jan 2021 16:09:37

US3622169

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:19:12
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'Contact Made (CONTACT MADE)'	Junlin Long (b) (4)	05 Jan 2021 16:09:37

US3622169

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:14:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:19:12
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered empty.	Junlin Long (b) (4)	05 Jan 2021 16:09:37

US3622169

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:34
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:19:18
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'Yes (Y)'	(b) (4) Junlin Long (b) (4) (b) (4)	05 Jan 2021 16:09:41

US3622169

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:14:19

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:34
User entered '1'	System	05 Jan 2021 16:09:41

US3622169

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:14:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:47:36
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:29
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Dec 2020 14:36:25

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 14:05:23
User entered 'USA-US085-2020-mRNA-1273-P301000005' Un-reviewed for Safety.	System	08 Dec 2020 00:22:40
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 00:22:40
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 20:22:35
User entered 'USA-US085-2020-mRNA-1273-P301000004' User entered 'New'	System	07 Dec 2020 20:20:22
	(b) (4), (b) (6)	07 Dec 2020 20:20:22

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Adverse event](#)

Audit	User	Time (GMT)
User closed query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	19 Feb 2021 04:40:50
' (Site from DM). Query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	Junlin Long (b) (4) (b) (4)	18 Feb 2021 13:15:21
' answered with 'based on medical records, this subject was covid-19 negative.' (Site from DM). User opened query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	15 Feb 2021 14:28:31
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Dyspnea exacerbated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 14:29:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 14:29:54
Data point term sent to Coder	System	07 Dec 2020 14:52:50
User entered 'worsening dyspnea'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '29 Nov 2020'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User closed query 'Per MM, please provide the end date.'" (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 04:40:57
Query 'Per MM, please provide the end date.'" answered with 'end date was provided as the date of expiration of participant.' (Site from DM).	Junlin Long (b) (4)	18 Feb 2021 13:32:11
DataPoint Un-verified.	Junlin Long (b) (4)	18 Feb 2021 13:31:05
User entered 'No (N)' reason for change: Per Query Resolution	Junlin Long (b) (4)	18 Feb 2021 13:31:05
User opened query 'Per MM, please provide the end date.'" (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 14:28:39
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User closed query 'Per CDM:Kindly clarify the response and update accordingly.Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 09:13:55
Query 'Per CDM:Kindly clarify the response and update accordingly.Thank you.' answered with 'participant expired on 21JAN2021 due to WORSENING METASTATIC HEPATOCELLULAR CARCINOMA.' (Site from DM).	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:04:35
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	19 Feb 2021 04:29:58
User opened query 'Per CDM:Kindly clarify the response and update accordingly.Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 04:29:54
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'end date was provided as the date of expiration of participant.' (Site from System).	Junlin Long (b) (4) (b) (4)	18 Feb 2021 13:32:53
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	18 Feb 2021 13:31:33
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	18 Feb 2021 13:31:05
User entered '21 Jan 2021' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	18 Feb 2021 13:31:05
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Severity](#)

Audit	User	Time (GMT)
User closed query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	18 Feb 2021 13:31:33
User opened query 'Outcome is Fatal, but Severity is not Grade 4. Please correct.' (Site from System).	System	18 Feb 2021 13:31:05
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '1'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered 'Unknown (UNKNOWN)' reason for change: Per Query Resolution	Junlin Long (b) (4)	18 Feb 2021 13:31:33
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	18 Feb 2021 13:31:05
User entered 'Fatal (FATAL)' reason for change: Per Query Resolution	(b) (4)	
	Junlin Long (b) (4)	18 Feb 2021 13:31:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Junlin Long (b) (4)	07 Dec 2020 14:52:49
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:14:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 14:52:49

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 14:06:04
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 00:24:36
User entered 'USA-US085-2020-mRNA-1273-P301000005' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 00:24:36
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 20:22:35
User entered 'USA-US085-2020-mRNA-1273-P301000004'	(b) (4), (b) (6)	07 Dec 2020 20:21:30

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Adverse event](#)

Audit	User	Time (GMT)
User closed query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	19 Feb 2021 04:41:04
' (Site from DM). Query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	Junlin Long (b) (4) (b) (4)	18 Feb 2021 13:22:32
' answered with 'based on medical records, this subject was covid-19 negative.' (Site from DM). User opened query "'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	15 Feb 2021 14:28:57
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 14:54:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 14:54:49
Data point term sent to Coder	System	07 Dec 2020 14:53:50
User entered 'nasal congestion'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '29 Nov 2020'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User closed query 'Per MM, please provide the end date.'" (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 04:41:07
Query 'Per MM, please provide the end date.'" answered with 'end date was provided as the date of expiration of participant.' (Site from DM).	Junlin Long (b) (4)	18 Feb 2021 13:34:09
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	18 Feb 2021 13:33:59
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	
	Junlin Long (b) (4)	18 Feb 2021 13:33:59
User opened query 'Per MM, please provide the end date.'" (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 14:29:03
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Yes (Y)'	(b) (4)	
	Junlin Long (b) (4)	07 Dec 2020 14:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User closed query 'Per CDM:Kindly clarify the response and update accordingly.Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 09:14:41
Query 'Per CDM:Kindly clarify the response and update accordingly.Thank you.' answered with 'participant expired on 21JAN2021 due to WORSENING METASTATIC HEPATOCELLULAR CARCINOMA.' (Site from DM).	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:04:43
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	19 Feb 2021 04:31:14
User opened query 'Per CDM:Kindly clarify the response and update accordingly.Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 04:31:10
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'end date was provided as the date of expiration of participant.' (Site from System).	Junlin Long (b) (4) (b) (4)	18 Feb 2021 13:34:14
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	18 Feb 2021 13:33:59
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	18 Feb 2021 13:33:59
User entered '21 Jan 2021' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	18 Feb 2021 13:33:59
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4)	07 Dec 2020 14:53:35
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '1'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
DataPoint Un-verified.	Junlin Long (b) (4)	18 Feb 2021 13:33:59
User entered 'Unknown (UNKNOWN)' reason for change: Per Query Resolution	Junlin Long (b) (4)	18 Feb 2021 13:33:59
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:14:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 14:53:35

US3622169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
Reviewed for Safety.	(b) (4), (b) (6)	07 Dec 2020 20:22:35
User entered 'USA-US085-2020-mRNA-1273-P301000004'	(b) (4), (b) (6)	07 Dec 2020 20:22:16

US3622169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 04:40:06
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'based on medical records, this subject was covid-19 negative.' (Site from DM).	Junlin Long (b) (4)	18 Feb 2021 13:22:57
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 14:29:19
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
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)	07 Dec 2020 15:10:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Dec 2020 15:10:49
Data point term sent to Coder	System	07 Dec 2020 15:10:03
User entered 'pneumonia'	Junlin Long (b) (4)	07 Dec 2020 15:09:11

US3622169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

US3622169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

US3622169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

US3622169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Symptoms of nasal congestion and worsening dyspnea have been reported starting on 29 Nov 2020. Please consider updating the event start date to reflect the date that the subject first experienced symptoms.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 15:24:53
Query 'PV Query: Symptoms of nasal congestion and worsening dyspnea have been reported starting on 29 Nov 2020. Please consider updating the event start date to reflect the date that the subject first experienced symptoms.' answered with 'based on medical records, participant was diagnosed with pneumonia on December 6, 2020 during hospitalization.' (Site from Safety).	Junlin Long (b) (4)	18 Feb 2021 13:24:56
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User opened query 'PV Query: Symptoms of nasal congestion and worsening dyspnea have been reported starting on 29 Nov 2020. Please consider updating the event start date to reflect the date that the subject first experienced symptoms.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 19:55:03
User entered '6 Dec 2020'	Junlin Long (b) (4)	07 Dec 2020 15:09:11

US3622169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

US3622169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 15:09:11

US3622169

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
DataPoint Un-verified.	Junlin Long (b) (4)	26 Jan 2021 18:03:02
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4)	26 Jan 2021 18:03:02
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Yes (Y)'	Junlin Long (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 14:59:30
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'based on medical records, participant was discharged on January 4th, 2021.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:05:05
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	26 Jan 2021 18:03:30
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	26 Jan 2021 18:03:30
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	26 Jan 2021 18:03:02
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:03:02
User entered '4 Jan 2021' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:03:02
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 19:54:43
User entered empty.	Junlin Long (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '1'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	26 Jan 2021 18:05:34
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		26 Jan 2021 18:05:34
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
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	07 Dec 2020 15:09:11
User entered '1'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '6 Dec 2020'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
DataPoint Un-verified.	Junlin Long (b) (4)	26 Jan 2021 18:05:34
User entered '4 Jan 2021' reason for change: Per Query Resolution	(b) (4)	26 Jan 2021 18:05:34
DataPoint Verified.	Junlin Long (b) (4)	19 Jan 2021 16:19:12
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 15:09:11
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 10:51:13
User opened query 'Per CDM:Response noted,however please consider to update the days from the records available at present.Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 10:49:25
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'based on information in hand during last data entry, participant had been in ICU for 4 days. based on current medical records provided by the hospital, participant was admitted to ICU on December 6th, 2020 and records do not show the number of days that participant was admitted to ICU.' (Site from System).	Junlin Long (b) (4) (b) (4)	19 Feb 2021 12:56:47
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	19 Feb 2021 12:51:34
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	19 Feb 2021 12:51:34
User entered empty; reason for change New Information	Junlin Long (b) (4) (b) (4)	19 Feb 2021 12:51:34
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '4' reason for change: New Information	Junlin Long (b) (4) (b) (4)	11 Dec 2020 19:26:00
User entered '1'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:14:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4)	07 Dec 2020 15:09:11
	(b) (4)	

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Form: Adverse Events (3)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4)	07 Dec 2020 15:09:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Concomitant medication checkbox is selected however, corresponding ConMed page is missing. Please consider to complete the ConMed forms. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 09:29:58
Query 'Per CDM: Concomitant medication checkbox is selected however, corresponding ConMed page is missing. Please consider to complete the ConMed forms. Thank you. ' answered with 'conmed page has been updated.' (Site from DM).	Junlin Long (b) (4)	19 Feb 2021 12:51:20
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User opened query 'Per CDM: Concomitant medication checkbox is selected however, corresponding ConMed page is missing. Please consider to complete the ConMed forms. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 14:54:27
User entered '1'	Junlin Long (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered '0'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
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)	27 Jan 2021 14:59:40
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 'based on medical records, participant was discharged from hospital on January 4th, 2021.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:08:09
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:03:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:03:30
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
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)	11 Dec 2020 19:54:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User entered empty.	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = CT SCAN DONE ON DECEMBER 06, 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:42:59
Query 'Per DM CLR: Narrative = CT SCAN DONE ON DECEMBER 06, 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'conproc updated' (Site from DM).	Junlin Long (b) (4)	09 Mar 2021 14:49:39
User closed query 'Per DM CLR: Narrative = CT GUIDED LIVER BIOPSY ON DECEMBER 30, 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 08:14:54
Query 'Per DM CLR: Narrative = CT GUIDED LIVER BIOPSY ON DECEMBER 30, 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'please refer to concomitant procedures page line 26.' (Site from DM).	Junlin Long (b) (4)	25 Feb 2021 19:15:29
User opened query 'Per DM CLR: Narrative = CT GUIDED LIVER BIOPSY ON DECEMBER 30, 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 01:29:23
User opened query 'Per DM CLR: Narrative = CT SCAN DONE ON DECEMBER 06, 2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 01:29:19
User closed query 'Per DM CLR: Note, SAE Narrative = Oxygen and antibiotics. Please review and ensure to include these in the CM ecrf. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 18:42:06

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 14:27:45
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 14:27:40
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 15:24:22
Query 'Per DM CLR: Note, SAE Narrative = Oxygen Junlin Long and antibiotics. Please review and ensure to include these in the CM ecrf. Else, clarify. ' answered with 'oxygen and antibiotics have been updated in conmed log.' (Site from DM).	(b) (4) (b) (4)	19 Feb 2021 14:01:13
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' answered with 'multiple attempts have been made to obtain discharge summary from the hospital with no success. fax attempts to obtain discharge summary made on 1/25/2021, 1/26/2021, 2/1/2021, 2/5/2021 and 2/18/2021. telephone attempts to obtain discharge summary made on 2/1/2021, 2/5/2021, 2/9/2021 and 2/17/2021.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	19 Feb 2021 13:10:34

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'conmed page and concomitant procedures page have been updated for this SAE.' (Site from Safety).	Junlin Long (b) (4)	19 Feb 2021 12:57:37
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'based on medical records, this subject was covid-19 negative.' (Site from Safety).	Junlin Long (b) (4)	18 Feb 2021 13:25:19
User opened query 'Per DM CLR: Note, SAE Narrative = Oxygen and antibiotics. Please review and ensure to include these in the CM ecrf. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 03:31:52
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 19:47:07

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Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT WAS INITIALLY CONTACTED FOR MONTH 3 SAFETY CALL ON DECEMBER 3RD, 2020 AND REPORTED NASAL CONGESTION AND WORSENING DYSPNEA SINCE NOVEMBER 29TH, 2020. AT THAT TIME, PARTICIPANT WAS TOLD TO COME IN FOR AN ILLNESS VISIT, BUT STATES THEY WOULD NOT BE ABLE TO COME IN AND RESCHEDULED FOR DECEMBER 4TH, 2020. HOWEVER, PARTICIPANT DID NOT COME ON DECEMBER 4TH, 2020. PARTICIPANT WAS CONTACTED ON DECEMBER 4TH, 2020 AFTER MISSING THEIR SCHEDULED ILLNESS VISIT AND REPORTED SYMPTOMS CONTINUED. PARTICIPANT WAS THEN OFFERED A HOME ILLNESS VISIT, BUT REFUSED AND INSISTED ON COMING IN ON MONDAY, DECEMBER 7TH, 2020. ON DECEMBER 7TH, 2020, PARTICIPANT WAS CONTACTED REGARDING THEIR MISSED SCHEDULED ILLNESS VISIT, TO WHICH THEY INFORMED US THEY WERE HOSPITALIZED SINCE DECEMBER 6TH, 2020. PARTICIPANT STATES THEY WERE DIAGNOSED WITH PNEUMONIA AND STARTED WITH O2 AND IV ANTIBIOTICS, BUT DO NOT RECALL EITHER DOSE. update: On December 06, 2020 the participant went to NorthShore Medical Center ER with chief complaint of shortness of breath, weakness, and abdominal pain x 3 days. The participant was admitted for pneumonia. In addition, CT scan done on December 06, 2020 revealed liver lesions and multiple lung nodules suggestive of hepatocellular carcinoma with lung metastases. Metastatic hepatocellular carcinoma was confirmed with CT guided liver biopsy on December 30, 2020. The participant was discharged on January 4, 2021. We have received only partial medical records from this admission but have requested full medical records to be sent. Once we receive full medical records, we will update admission information.' reason for change: New Information	Junlin Long (b) (4)	26 Jan 2021 19:47:07

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:12
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 19:54:28
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 19:54:22
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 19:54:14
User entered 'participant was initially contacted for month 3 safety call on December 3rd, 2020 and reported nasal congestion and worsening dyspnea since November 29th, 2020. at that time, participant was told to come in for an illness visit, but states they would not be able to come in and rescheduled for December 4th, 2020. however, participant did not come on December 4th, 2020. participant was contacted on December 4th, 2020 after missing their scheduled illness visit and reported symptoms continued. participant was then offered a home illness visit, but refused and insisted on coming in on Monday, December 7th, 2020. On December 7th, 2020, participant was contacted regarding their missed scheduled illness visit, to which they informed us they were hospitalized since December 6th, 2020. participant states they were diagnosed with pneumonia and started with O2 and IV antibiotics, but do not recall either dose.'	Junlin Long (b) (4) (b) (4)	07 Dec 2020 15:09:11

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	07 Dec 2020 15:09:11

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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)
User entered '1'	System	07 Dec 2020 15:09:11

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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)
User entered '1'	System	07 Dec 2020 15:09:11

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 13:56:24
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'USA-US085-2020-mRNA-1273-P301000004'	(b) (4), (b) (6)	27 Jan 2021 15:23:27

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Hepatobiliary neoplasms malignant and unspecified, HLT: Hepatic neoplasms malignant, PT: Hepatocellular carcinoma, LLT: Hepatocellular carcinoma metastatic - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Jan 2021 17:13:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Jan 2021 17:13:16
Data point term sent to Coder	System	26 Jan 2021 14:03:42
User entered 'metastatic hepatocellular carcinoma'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:03:01

US3622169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Jan 2021 14:03:01
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:03:01

US3622169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'No (N)'	Junlin Long (b) (4)	26 Jan 2021 14:03:01
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '30 Dec 2020'	Junlin Long (b) (4)	26 Jan 2021 14:03:01
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered empty.	Junlin Long (b) (4)	26 Jan 2021 14:03:01
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	05 Feb 2021 15:17:28
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 15:17:08
User entered empty.	System	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
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 DM).	(b) (4), (b) (6)	27 Apr 2021 10:48:34
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 'Event end date has already been provided.' (Site from DM).	Junlin Long (b) (4)	26 Apr 2021 13:42:06
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 DM).	(b) (4), (b) (6)	23 Apr 2021 18:56:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
DataPoint Un-verified.	Junlin Long (b) (4)	18 Feb 2021 13:50:21
User entered 'No (N)' reason for change: New Information	Junlin Long (b) (4)	18 Feb 2021 13:50:21
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered '4 Jan 2021' reason for change: New Information	Junlin Long (b) (4)	19 Feb 2021 14:09:48
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	18 Feb 2021 13:50:48
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	18 Feb 2021 13:50:48
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	18 Feb 2021 13:50:21
DataPoint Un-verified.	Junlin Long (b) (4)	18 Feb 2021 13:50:21
User entered '21 Jan 2021' reason for change: New Information	Junlin Long (b) (4)	18 Feb 2021 13:50:21
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered empty.	Junlin Long (b) (4)	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered empty.	Junlin Long (b) (4)	26 Jan 2021 14:03:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	28 Apr 2021 00:05:44
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 15:18:09
User entered empty.	System	26 Jan 2021 14:03:01

US3622169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:03:01

US3622169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:03:01

US3622169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '0'	Junlin Long (b) (4)	26 Jan 2021 14:03:01
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:03:01

US3622169

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '1'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '6 Dec 2020'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '4 Jan 2021'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 10:52:26
User opened query 'Per CDM:Response noted,however kindly consider to update the data from the records available at present.Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 10:52:21
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'based on current medical records provided by the hospital, participant was admitted to ICU on December 6th, 2020 and records do not show the number of days that participant was admitted to ICU.' (Site from System).	Junlin Long (b) (4) (b) (4)	19 Feb 2021 14:04:19
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	26 Jan 2021 14:03:01
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '0'	Junlin Long (b) (4)	26 Jan 2021 14:03:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '0'	Junlin Long (b) (4)	26 Jan 2021 14:03:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4)	26 Jan 2021 14:03:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:43:11
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'according to medical records, no specific medication was given to treat this SAE and procedures were for diagnostic purpose.' (Site from DM).	Junlin Long (b) (4)	09 Mar 2021 14:54:11
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 01:30:36
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '1'	Junlin Long (b) (4)	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '0'	Junlin Long (b) (4)	26 Jan 2021 14:03:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '0'	Junlin Long (b) (4)	26 Jan 2021 14:03:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
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)	19 Feb 2021 14:43:15
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	19 Feb 2021 14:09:48
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 'based on medical records, participant expired on January 21, 2021.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	18 Feb 2021 13:51:26
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	18 Feb 2021 13:50:48
User entered 'Fatal (FATAL)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	18 Feb 2021 13:50:48
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)	05 Feb 2021 15:15:53
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Unknown (UNKNOWN)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:03:01

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	19 Feb 2021 14:11:44
DataPoint Un-verified.	Junlin Long (b) (4)	19 Feb 2021 14:11:44
User entered 'METASTATIC HEPATOCELLULAR CARCINOMA' reason for change: Per Query Resolution	Junlin Long (b) (4)	19 Feb 2021 14:11:44
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	19 Feb 2021 14:09:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered empty.	Junlin Long (b) (4)	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 13:56:13
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'medical records for the first hospital admission which includes SAEs for pneumonia and metastatic hepatocellular carcinoma have been sent to the provided email address.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	22 Feb 2021 18:38:02
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 14:28:12
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'conmed page and concomitant procedures page have been updated.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	19 Feb 2021 14:18:12
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Feb 2021 17:34:06

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	18 Feb 2021 17:34:06
DataPoint Un-verified.	Junlin Long (b) (4)	18 Feb 2021 17:34:06
User entered 'After review of medical records received it was found that on December 06, 2020 the participant went to NorthShore Medical Center ER with chief complaint of shortness of breath, weakness, and abdominal pain x 3 days. The participant was admitted to the ICU on December 06, 2021. Diagnoses included pneumonia, dyspnea, and hypocalcemia. CT scan done on December 06, 2020 revealed liver lesions and multiple lung nodules suggestive of hepatocellular carcinoma with lung metastases. Metastatic hepatocellular carcinoma was confirmed with CT guided liver biopsy on December 30, 2020. He was found to have a large right pleural effusion and underwent right thoracentesis on 12/11/2020 and right pleural drain placement under U/S guidance on 12/15/2020. The participant was discharged from the hospital on January 4, 2021. Hospital records received to date do not show when the patient was discharged from ICU. Multiple requests have been made for discharge summary and physician progress notes and still have not been received.	Junlin Long (b) (4)	18 Feb 2021 17:34:06
Relevant labs include:		
12/06/2020 platelets 99 (L), calcium 8.4 (L), alk phos 280 (H), total bili 1.9 (H), ALT 55 (H), AST 94 (H)		
12/28/2020 sodium 131 (L), calcium 8.0 (L), AST 7.2 (H), M Pneumo IgM positive, SARS Ag negative, COVID 19 PCR negative' reason for change: New Information		
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).	(b) (4), (b) (6)	05 Feb 2021 15:14:05

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 15:13:42
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 15:08:10
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)	05 Feb 2021 15:07:34
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 15:07:15
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Jan 2021 14:03:01
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:14:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 14:03:01

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:02
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 14:22:50
DataPoint Un-verified.	(b) (4), (b) (6)	22 Feb 2021 14:19:06
User entered 'USA-US085-2020-mRNA-1273-P301000004' reason for change: New Information	(b) (4), (b) (6)	22 Feb 2021 14:19:06
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'USA-US085-2021-mRNA-1273-P301000008' User entered 'New'	System	27 Jan 2021 15:24:30
	(b) (4), (b) (6)	27 Jan 2021 15:24:30

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:04
User closed query 'PV Query: Please confirm if cardio-pulmonary arrest should be an additional event with fatal outcome. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 16:28:19
Query 'PV Query: Please confirm if cardio-pulmonary arrest should be an additional event with fatal outcome. ' answered with 'cardio-pulmonary arrest should not be an independent sae. it's related to participant's late-stage metastatic hepatocellular carcinoma.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	10 Mar 2021 16:54:38
User closed query 'PV Query- Please confirm if bilateral pleural effusion, anasarca, and sepsis meets the criteria of SAE.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:27:14
Query 'PV Query- Please confirm if bilateral pleural effusion, anasarca, and sepsis meets the criteria of SAE.' answered with 'bilateral pleural effusion, anasarca, and sepsis were secondary to this SAE.' (Site from Safety).	Junlin Long (b) (4) (b) (4)	09 Mar 2021 14:56:50
User opened query 'PV Query: Please confirm if cardio-pulmonary arrest should be an additional event with fatal outcome. ' (Site from Safety).	(b) (4), (b) (6)	27 Feb 2021 00:56:57
User opened query 'PV Query- Please confirm if bilateral pleural effusion, anasarca, and sepsis meets the criteria of SAE.' (Site from Safety).	(b) (4), (b) (6)	27 Feb 2021 00:56:17
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Hepatobiliary neoplasms malignant and unspecified, HLT: Hepatic neoplasms malignant, PT: Hepatocellular carcinoma, LLT: Hepatocellular carcinoma metastatic - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 15:56:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 15:56:58
Data point term sent to Coder	System	19 Feb 2021 14:47:14
User entered 'WORSENING METASTATIC HEPATOCELLULAR CARCINOMA' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	19 Feb 2021 14:47:03
Data point term sent to Coder	System	19 Feb 2021 14:46:14
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	19 Feb 2021 14:45:44

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Junlin Long (b) (4)	19 Feb 2021 14:45:44
	(b) (4)	
User entered 'worsening CARDIOPULMONARY ARREST' reason for change: New Information DataPoint Verified.	Junlin Long (b) (4)	19 Feb 2021 14:45:44
	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Cardio-respiratory arrest, LLT: Cardiopulmonary arrest - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 18:35:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Jan 2021 18:35:54
	(b) (4)	
Data point term sent to Coder	System	26 Jan 2021 18:34:48
User entered 'cardiopulmonary arrest'	Junlin Long (b) (4)	26 Jan 2021 18:34:32
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
DataPoint Un-verified.	Junlin Long (b) (4)	19 Feb 2021 14:45:44
User entered '16 Jan 2021' reason for change: New Information	Junlin Long (b) (4)	19 Feb 2021 14:45:44
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '21 Jan 2021'	Junlin Long (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'No (N)'	Junlin Long (b) (4)	26 Jan 2021 18:34:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '21 Jan 2021'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered empty.	Junlin Long (b) (4)	26 Jan 2021 18:34:32
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Grade 4 (Grade 4)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Yes (Y)'	Junlin Long (b) (4)	26 Jan 2021 18:34:32
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '1'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '0'	Junlin Long (b) (4)	26 Jan 2021 18:34:32
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '1'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '16 Jan 2021'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '21 Jan 2021'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '4'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4)	26 Jan 2021 18:34:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
DataPoint Un-verified.	Junlin Long (b) (4)	19 Feb 2021 14:48:09
User entered '0' reason for change: New Information	(b) (4)	19 Feb 2021 14:48:09
DataPoint Verified.	Junlin Long (b) (4)	02 Feb 2021 15:20:32
User entered '1'	(b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
DataPoint Un-verified.	Junlin Long (b) (4)	19 Feb 2021 14:48:09
User entered '1' reason for change: New Information	(b) (4)	19 Feb 2021 14:48:09
DataPoint Verified.	Junlin Long (b) (4)	02 Feb 2021 15:20:32
User entered '0'	(b) (4)	26 Jan 2021 18:34:32

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:43:39
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'procedures were done for diagnostic purpose.' (Site from DM).	Junlin Long (b) (4) (b) (4)	09 Mar 2021 14:58:31
User entered '0' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	09 Mar 2021 14:58:09
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 06:58:04
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	19 Feb 2021 14:48:09
User entered '1' reason for change: New Information	Junlin Long (b) (4) (b) (4)	19 Feb 2021 14:48:09
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered '0'	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'Fatal (FATAL)'	Junlin Long (b) (4)	26 Jan 2021 18:34:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered empty.	Junlin Long (b) (4) (b) (4)	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User closed query 'Per DM CLR: Narrative = MULTIPLE SYNCOPAL EPISODES, WORSENING EDEMA, RIGHT UPPER QUADRANT PAIN, AND FATIGUE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 05:46:07
Query 'Per DM CLR: Narrative = MULTIPLE SYNCOPAL EPISODES, WORSENING EDEMA, RIGHT UPPER QUADRANT PAIN, AND FATIGUE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. Otherwise, clarify. ' answered with 'MULTIPLE SYNCOPAL EPISODES, WORSENING EDEMA, RIGHT UPPER QUADRANT PAIN, AND FATIGUE were secondary to this SAE.' (Site from DM).	Junlin Long (b) (4) (b) (4)	09 Mar 2021 14:59:30
User opened query 'Per DM CLR: Narrative = MULTIPLE SYNCOPAL EPISODES, WORSENING EDEMA, RIGHT UPPER QUADRANT PAIN, AND FATIGUE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 01:31:37
Data entry unlocked.	(b) (4), (b) (6)	25 Feb 2021 01:31:33
Data entry locked.	(b) (4), (b) (6)	25 Feb 2021 01:31:29
User closed query 'PV Query: The narrative states the subject was hospitalized due to "multiple syncopal episodes, worsening edema, worsening shortness of breath, right upper quadrant pain, and fatigue." Please assess whether these events meet criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 14:28:52

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 14:28:47
User closed query 'PV Query: Please provide further details of death.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 14:28:41
User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 14:28:31
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'participant was tested negative for covid-19 on 16JAN2021.' (Site from Safety).	Junlin Long (b) (4)	19 Feb 2021 15:45:27
Query 'PV Query: The narrative states the subject was hospitalized due to "multiple syncopal episodes, worsening edema, worsening shortness of breath, right upper quadrant pain, and fatigue." Please assess whether these events meet criteria for separate AE/SAE reporting.' answered with 'narrative has been updated with PI notes.' (Site from Safety).	Junlin Long (b) (4)	19 Feb 2021 15:01:58
Query 'PV Query: Please provide further details of death.' answered with 'narrative has been updated with PI notes.' (Site from Safety).	Junlin Long (b) (4)	19 Feb 2021 15:00:25
Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' answered with 'medical records do not state an autopsy was performed.' (Site from Safety).	Junlin Long (b) (4)	19 Feb 2021 15:00:07
DataPoint Un-verified.	Junlin Long (b) (4)	19 Feb 2021 14:58:13

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Narrative](#)

Audit	User	Time (GMT)
User entered 'BASED ON MEDICAL RECORDS OBTAINED, PARTICIPANT WENT INTO CARDIOPULMONARY ARREST AND EXPIRED ON JANUARY 21, 2021. UPDATE: THE PARTICIPANT WENT TO THE HOSPITAL ON JANUARY 16, 2021. CHIEF COMPLAINT WAS MULTIPLE SYNCOPAL EPISODES, WORSENING EDEMA, WORSENING SHORTNESS OF BREATH, RIGHT UPPER QUADRANT PAIN, AND FATIGUE. HE WAS ADMITTED TO ICU AND WENT INTO CARDIOPULMONARY ARREST ON JANUARY 21, 2021. WE ARE AWAITING FULL MEDICAL RECORDS TO REVIEW AND UPDATE INFORMATION. update (pi notes): discussed with team monitor, second admission primary diagnosis is worsening/exacerbation of METASTATIC HEPATOCELLULAR CARCINOMA. all subsequent hospital events including anasarca, sepsis, death are secondary to this diagnosis. will change sae term to WORSENING METASTATIC HEPATOCELLULAR CARCINOMA rather than cardiopulmonary arrest. other aes to be entered as align to conmeds (e.g., antibiotics).' reason for change: New Information	Junlin Long (b) (4) (b) (4)	19 Feb 2021 14:58:13
User opened query 'PV Query: The narrative states the subject was hospitalized due to "multiple syncopal episodes, worsening edema, worsening shortness of breath, right upper quadrant pain, and fatigue." Please assess whether these events meet criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Feb 2021 15:57:02
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Feb 2021 15:56:53
User opened query 'PV Query: Please provide further details of death.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Feb 2021 15:56:45

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 15:56:40
	(b) (4), (b) (6)	02 Feb 2021 15:20:32
User entered 'BASED ON MEDICAL RECORDS OBTAINED, PARTICIPANT WENT INTO CARDIOPULMONARY ARREST AND EXPIRED ON JANUARY 21, 2021.	Junlin Long (b) (4)	26 Jan 2021 19:48:02
	(b) (4)	
update: The participant went to the hospital on January 16, 2021. Chief complaint was multiple syncopal episodes, worsening edema, worsening shortness of breath, right upper quadrant pain, and fatigue. He was admitted to ICU and went into cardiopulmonary arrest on January 21, 2021. We are awaiting full medical records to review and update information.' reason for change: New Information		
User entered 'based on medical records obtained, participant went into cardiopulmonary arrest and expired on January 21, 2021.'	Junlin Long (b) (4)	26 Jan 2021 18:34:32
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 18:34:32

US3622169

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:14:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 18:34:32

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 15:13:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 15:13:49
Data point term sent to Coder	System	19 Feb 2021 15:12:43
User entered 'sepsis'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered 'Yes (Y)'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered '16 Jan 2021'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered empty.	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 11:26:44
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'participant expired on 21JAN2021 due to WORSENING METASTATIC HEPATOCELLULAR CARCINOMA. as a result, the outcome of sepsis was entered as unknown.' (Site from System).	Junlin Long (b) (4)	19 Feb 2021 15:13:33
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	
User entered '21 Jan 2021'	System	19 Feb 2021 15:12:10
	Junlin Long (b) (4)	19 Feb 2021 15:12:10
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered empty.	Junlin Long (b) (4)	19 Feb 2021 15:12:10
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered 'Grade 3/Severe (Grade 3/Severe)'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered 'No (N)'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered '0'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered '0'	Junlin Long (b) (4)	19 Feb 2021 15:12:10
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered '0'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered empty.	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered empty.	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered empty.	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered empty.	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered '0'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered '0'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered '0'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered 'Not Related (NOT RELATED)'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered 'Not Applicable (NOT APPLICABLE)'	Junlin Long (b) (4)	19 Feb 2021 15:12:10
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered '0'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered '1'	Junlin Long (b) (4)	19 Feb 2021 15:12:10
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered '0'	Junlin Long (b) (4)	19 Feb 2021 15:12:10
	(b) (4)	

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered 'Unknown (UNKNOWN)'	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered empty.	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:10
User entered empty.	Junlin Long (b) (4) (b) (4)	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Feb 2021 15:12:10

US3622169

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:14:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 15:12:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:14:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:59:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:34
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:20:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Sep 2020 21:22:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 21:22:45
Data point term sent to Coder User entered 'Furosemide'	System (b) (4), (b) (6)	10 Sep 2020 21:21:44 10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Fluid retention'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:13:49
Signature has been broken.	Junlin Long (b) (4) (b) (4)	09 Mar 2021 15:01:23
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '50'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:13:49
Signature has been broken.	Junlin Long (b) (4) (b) (4)	09 Mar 2021 15:01:27
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 21:21:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 08:09:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 08:09:48
Data point term sent to Coder User entered 'Spironolactone'	System (b) (4), (b) (6)	10 Sep 2020 21:22:49 10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Fluid retention'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '40'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Sep 2020 21:22:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
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)	07 Oct 2020 15:15:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	07 Oct 2020 15:15:22
Data point term sent to Coder Coding entries removed.	System	07 Oct 2020 14:15:09
	Junlin Long (b) (4)	07 Oct 2020 14:14:44
User signature succeeded.	(b) (4)	
	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
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)	10 Sep 2020 21:25:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	10 Sep 2020 21:25:49
Data point term sent to Coder	System	10 Sep 2020 21:24:50
User entered 'Flu vaccine'	(b) (4), (b) (6)	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	08 Oct 2020 13:42:12
User closed query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 04:07:25
' (Site from DM).		
Query 'Per DM CLR: Please update the indication of Junlin Long this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	(b) (4) (b) (4)	07 Oct 2020 14:14:54
' answered with 'indication updated' (Site from DM).		
Signature has been broken.	Junlin Long (b) (4) (b) (4)	07 Oct 2020 14:14:44
User entered 'influenza PROPHYLAXIS' reason for change: Data Entry Error	Junlin Long (b) (4) (b) (4)	07 Oct 2020 14:14:44
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	03 Oct 2020 06:41:36
' (Site from DM).		
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Prophylaxis'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Injection'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Annually'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '25 Aug 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 21:24:30

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Sep 2020 01:05:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 01:05:48
Data point term sent to Coder	System	10 Sep 2020 21:26:57
User entered 'Albuterol'	(b) (4), (b) (6)	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Dyspnea'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 04:03:55
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'ppt does not know the dose' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 15:02:11
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 06:42:00
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '2'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'puff (PUFF)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	13 Sep 2020 16:37:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 21:26:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
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.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 17:59:53
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 17:59:53
Data point term sent to Coder	System	18 Feb 2021 17:58:52
User entered 'CEFTRIAXONE'	(b) (4), (b) (6)	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'PNEUMONIA'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '1'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
User entered empty.	System	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
User entered empty.	System	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:20
User entered empty.	System	18 Feb 2021 17:58:28

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
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: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:00:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:00:53
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	18 Feb 2021 17:59:53
User entered 'SOLUMEDROL'	(b) (4), (b) (6)	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '125'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
User entered empty.	System	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
User entered empty.	System	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:44
User entered empty.	System	18 Feb 2021 17:59:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
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: DUONEB - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 00:53:05
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 00:53:05
Data point term sent to Coder	System	18 Feb 2021 19:11:49
Data point term sent to Coder	System	18 Feb 2021 18:02:59
Data point term sent to Coder	System	18 Feb 2021 18:01:54
User entered 'DUONEB'	(b) (4), (b) (6)	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Feb 2021 18:02:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:02:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:02:52
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 18:01:15
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Feb 2021 18:02:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:02:52
User entered 'PNEUMONIA' reason for change:	(b) (4), (b) (6)	18 Feb 2021 18:02:52
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 18:01:15
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Feb 2021 18:02:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:02:52
User entered '3' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:02:52
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 18:01:15
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Feb 2021 18:02:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:02:52
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:02:52
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 18:01:15
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Feb 2021 18:02:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:02:52
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:02:52
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 18:01:15
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:11:22
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 18:02:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:02:52
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:02:52
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 18:01:15
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'NEBULIZER' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 19:11:22
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	18 Feb 2021 18:02:52
User entered '6 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:02:52
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	18 Feb 2021 18:01:15
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Feb 2021 18:02:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:02:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:02:52
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 18:01:15
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	18 Feb 2021 18:02:59
User entered '04 Jan 2021' reason for change: Data Entry Error	System	18 Feb 2021 18:02:59
User opened query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4), (b) (6)	18 Feb 2021 18:02:52
User entered '04 Jan 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:02:52
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Feb 2021 18:02:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:02:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:02:52
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 18:01:15
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
User entered empty.	System	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
User entered empty.	System	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:48
User entered empty.	System	18 Feb 2021 18:01:15

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 07:29:05
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 07:29:05
Data point term sent to Coder	System	18 Feb 2021 18:05:01
User entered 'FUROSEMIDE'	(b) (4), (b) (6)	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '40'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '6 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '22 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
User entered empty.	System	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
User entered empty.	System	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:53
User entered empty.	System	18 Feb 2021 18:04:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
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: CALCIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 21:20:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 21:20:04
Data point term sent to Coder	System	18 Feb 2021 18:08:04
User entered 'CALCIUM CHLORIDE'	(b) (4), (b) (6)	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '1'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
User entered empty.	System	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
User entered empty.	System	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:38:58
User entered empty.	System	18 Feb 2021 18:07:08

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
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.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 18:11:53
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 18:11:53
Data point term sent to Coder	System	18 Feb 2021 18:11:05
User entered 'AZITHROMYCIN'	(b) (4), (b) (6)	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'PNEUMONIA'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '500'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
User entered '1'	System	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
User entered '1'	System	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:03
User entered '804 (804)'	System	18 Feb 2021 18:10:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
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) (b) (4)	24 Feb 2021 19:07:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 19:07:02
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	18 Feb 2021 18:13:08
User entered 'ZINC SULFATE'	(b) (4), (b) (6)	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:15:29
User entered 'No (N)'	(b) (4), (b) (6)	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'VITAMIN SUPPLEMENTATION'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '220'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	18 Feb 2021 18:13:20
User entered '04 Jan 2021' reason for change: Data Entry Error	System	18 Feb 2021 18:13:20
User opened query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4), (b) (6)	18 Feb 2021 18:12:55
User entered '04 Jan 2020'	(b) (4), (b) (6)	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
User entered '1'	System	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
User entered '1'	System	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:07
User entered '804 (804)'	System	18 Feb 2021 18:12:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
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) (b) (4)	28 Feb 2021 17:05:27
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 17:05:27
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	18 Feb 2021 18:15:09
User entered 'VITAMIN C'	(b) (4), (b) (6)	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'VITAMIN SUPPLEMENTATION'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '1,000'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
User entered '1'	System	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
User entered '1'	System	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:12
User entered '804 (804)'	System	18 Feb 2021 18:14:54

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOPAMIDOL, PRODUCTSYNONYM: ISOVUE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 08:21:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 08:21:46
Data point term sent to Coder	System	18 Feb 2021 18:21:18
User entered 'IOPAMIDOL (ISOVUE)'	(b) (4), (b) (6)	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '370'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 19:14:14
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '09 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
User entered empty.	System	18 Feb 2021 19:14:14
User entered '1'	System	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
User entered empty.	System	18 Feb 2021 19:14:14
User entered '1'	System	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:18
User entered empty.	System	18 Feb 2021 19:14:14
User entered '804 (804)'	System	18 Feb 2021 18:20:27

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 07:36:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 07:36:10
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder System		18 Feb 2021 18:28:30
User entered 'SPIRONOLACTONE'	(b) (4), (b) (6)	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '50'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '22 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
User entered '1'	System	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
User entered '1'	System	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:44
User entered '804 (804)'	System	18 Feb 2021 18:28:06

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 18:31:53
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 18:31:53
Data point term sent to Coder	System	18 Feb 2021 18:30:32
User entered 'tylenol'	(b) (4), (b) (6)	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '650'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
User entered empty.	System	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
User entered empty.	System	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:39:45
User entered empty.	System	18 Feb 2021 18:29:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
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.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 17:50:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 17:50:52
Data point term sent to Coder	System	18 Feb 2021 18:34:35
User entered 'heparin'	(b) (4), (b) (6)	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '5,000'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '6 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
User entered '2'	System	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
User entered '1'	System	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:24
User entered '804 (804)'	System	18 Feb 2021 18:33:52

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
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: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 18:36:53
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 18:36:53
Data point term sent to Coder	System	18 Feb 2021 18:35:39
User entered 'VITAMIN D3'	(b) (4), (b) (6)	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'VITAMIN SUPPLEMENTATION'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '2000'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '7 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Feb 2021 18:35:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:35:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:35:48
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 18:35:38
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
User entered '1'	System	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
User entered '1'	System	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:11
User entered '804 (804)'	System	18 Feb 2021 18:35:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
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.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 18:39:54
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 18:39:54
Data point term sent to Coder	System	18 Feb 2021 18:38:41
User entered 'AZITHROMYCIN'	(b) (4), (b) (6)	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'PNEUMONIA'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '500'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '08 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '3 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
User entered '1'	System	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
User entered '1'	System	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:15
User entered '804 (804)'	System	18 Feb 2021 18:37:53

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: LACTULOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 12:27:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 12:27:14
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	18 Feb 2021 18:40:44
User entered 'LACTULOSE'	(b) (4), (b) (6)	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '8 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
User entered empty.	System	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
User entered empty.	System	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:22
User entered empty.	System	18 Feb 2021 18:39:45

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	(b) (4)	
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 18:43:59
Data point term sent to Coder	System	18 Feb 2021 18:42:46
User entered 'ROCEPHIN'	(b) (4), (b) (6)	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'PNEUMONIA'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '1'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '08 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
User entered '1'	System	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
User entered '1'	System	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:30
User entered '804 (804)'	System	18 Feb 2021 18:42:01

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
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)	05 Mar 2021 05:30:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:30:46
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	18 Feb 2021 18:43:49
User entered 'QUETIAPINE'	(b) (4), (b) (6)	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '50'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '8 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '3 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
User entered '1'	System	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
User entered '1'	System	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:34
User entered '804 (804)'	System	18 Feb 2021 18:43:41

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
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) (b) (4)	31 Mar 2021 13:29:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:29:23
Data point term sent to Coder	System	25 Mar 2021 13:52:44
Coding entries removed.	Junlin Long (b) (4)	25 Mar 2021 13:52:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
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) (b) (4)	18 Feb 2021 18:45:55
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 18:45:55
Data point term sent to Coder	System	18 Feb 2021 18:44:51
User entered 'LORAZEPAM'	(b) (4), (b) (6)	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:13
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). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:01:08
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'indication unknown (according to medical records)' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6) Junlin Long (b) (4) (b) (4)	25 Mar 2021 17:26:09 25 Mar 2021 13:52:30
Signature has been broken.	Junlin Long (b) (4) (b) (4)	25 Mar 2021 13:52:01
User entered 'unknown (according to medical records)' reason for change: Per Query Resolution DataPoint Verified.	Junlin Long (b) (4) (b) (4) (b) (4), (b) (6)	25 Mar 2021 13:52:01 24 Mar 2021 11:13:49
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). User signature succeeded.	(b) (4), (b) (6) Susanne Doblecki-Lewis	09 Mar 2021 06:01:49 19 Feb 2021 20:13:26
User entered 'ANXIETY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '2'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '9 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Feb 2021 18:45:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:45:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:45:15
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 18:44:48
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '3 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Feb 2021 18:45:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:45:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:45:15
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 18:44:48
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
User entered '1'	System	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
User entered '1'	System	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:38
User entered '804 (804)'	System	18 Feb 2021 18:44:48

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
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: CODEINE;GUAIFENESIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 22:36:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 22:36:04
Data point term sent to Coder	System	18 Feb 2021 18:46:56
User entered 'CODEINE-GUAIFENESIN'	(b) (4), (b) (6)	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'COUGH'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '10'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:47:10
User entered '11 Jan 2021'	(b) (4), (b) (6)	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	18 Feb 2021 18:47:10
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	18 Feb 2021 18:46:43
User entered '4 Jan 2021'	(b) (4), (b) (6)	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
User entered empty.	System	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
User entered empty.	System	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:42
User entered empty.	System	18 Feb 2021 18:46:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: NADOLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 11:29:48
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 11:29:48
Data point term sent to Coder	System	18 Feb 2021 18:49:05
User entered 'NADOLOL'	(b) (4), (b) (6)	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:20:59
User entered 'as needed (PRN)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 19:18:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '12 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 19:20:59
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 19:19:21
User entered '14 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 19:18:51
User entered '12 Dec 2020'	(b) (4), (b) (6)	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Feb 2021 18:48:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:48:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:48:39
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 18:48:26
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '31 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:20:59
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	18 Feb 2021 19:19:08
User entered '4 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 19:19:08
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	18 Feb 2021 19:19:01
User closed query 'End date is prior to start date. Please correct.' (Site from System).	System	18 Feb 2021 19:19:01
User entered '4 Jan 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 19:19:01
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	18 Feb 2021 19:18:51
User entered '4 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 19:18:51
User entered '31 Dec 2020'	(b) (4), (b) (6)	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
User entered '1'	System	18 Feb 2021 19:20:59
User entered empty.	System	18 Feb 2021 19:18:51
User entered '1'	System	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
User entered '1'	System	18 Feb 2021 19:20:59
User entered empty.	System	18 Feb 2021 19:18:51
User entered '1'	System	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:49:54
User entered '804 (804)'	System	18 Feb 2021 19:20:59
User entered empty.	System	18 Feb 2021 19:18:51
User entered '804 (804)'	System	18 Feb 2021 18:48:26

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
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) (b) (4)	20 Feb 2021 13:57:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 13:57:48
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	18 Feb 2021 18:53:08
User entered 'HUMAN ALBUMIN'	(b) (4), (b) (6)	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '50'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '22 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
User entered empty.	System	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
User entered empty.	System	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:02
User entered empty.	System	18 Feb 2021 18:52:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 19:08:53
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 19:08:53
Data point term sent to Coder	System	18 Feb 2021 18:54:09
Data point term sent to Coder	System	18 Feb 2021 18:53:08
User entered 'ZOSYN'	(b) (4), (b) (6)	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Feb 2021 18:53:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:53:24
User entered 'PNEUMONIA' reason for change:	(b) (4), (b) (6)	18 Feb 2021 18:53:24
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 18:53:04
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '3.375'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
User entered '2'	System	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
User entered '1'	System	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:23
User entered '804 (804)'	System	18 Feb 2021 18:53:04

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
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.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 18:55:53
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 18:55:53
Data point term sent to Coder	System	18 Feb 2021 18:55:09
User entered 'VANCOMYCIN'	(b) (4), (b) (6)	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'PNEUMONIA'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '1000'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '24 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Feb 2021 18:55:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 18:55:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:55:01
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 18:54:34
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	18 Feb 2021 18:55:01
User entered '26 Dec 2020' reason for change: Data Entry Error	System	18 Feb 2021 18:55:01
User opened query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4), (b) (6)	18 Feb 2021 18:54:34
User entered '23 Dec 2020'	(b) (4), (b) (6)	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
User entered '2'	System	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
User entered '1'	System	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:35
User entered '804 (804)'	System	18 Feb 2021 18:54:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 18:57:53
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 18:57:53
Data point term sent to Coder	System	18 Feb 2021 18:57:11
User entered 'ZOFRAN'	(b) (4), (b) (6)	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'NAUSEA'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '4'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '24 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'End Date is after Date of Death. Please review and reconcile.' (Site from System).	(b) (4)	18 Feb 2021 18:56:46
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	18 Feb 2021 18:56:46
User entered '4 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 18:56:46
User opened query 'End Date is after Date of Death. Please review and reconcile.' (Site from System).	System	18 Feb 2021 18:56:17
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	18 Feb 2021 18:56:17
User entered '4 Feb 2021'	(b) (4), (b) (6)	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
User entered empty.	System	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
User entered empty.	System	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:40
User entered empty.	System	18 Feb 2021 18:56:17

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
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) (b) (4)	25 Mar 2021 13:56:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 13:56:27
Data point term sent to Coder	System	25 Mar 2021 13:55:51
Coding entries removed.	Junlin Long (b) (4)	25 Mar 2021 13:55:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
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) (b) (4)	18 Feb 2021 18:59:54
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 18:59:54
Data point term sent to Coder	System	18 Feb 2021 18:59:13
User entered 'FAMOTIDINE'	(b) (4), (b) (6)	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:13
User closed query 'Per CDM:RQ: Response provided as 'updated' However, Medical history or AE that matches this Con med indication has not been updated yet. Please review and update appropriately else clarify. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 09:19:56
Query 'Per CDM:RQ: Response provided as 'updated' Junlin Long However, Medical history or AE that matches this Con med indication has not been updated yet. Please review and update appropriately else clarify. Thank you ' answered with 'Indication has been updated as "reflux prevention", so no MH or AE should be added.' (Site from DM).	(b) (4) (b) (4)	06 Apr 2021 15:48:30
User opened query 'Per CDM:RQ: Response provided as 'updated' However, Medical history or AE that matches this Con med indication has not been updated yet. Please review and update appropriately else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 13:16:07
Query 'Per CDM:RQ: Response provided as 'updated' However, there is Medical history or AE that matches this Con med indication has been updated yet. Please review and update appropriately else clarify. Thank you ' canceled (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 13:14:59
User opened query 'Per CDM:RQ: Response provided as 'updated' However, there is Medical history or AE that matches this Con med indication has been updated yet. Please review and update appropriately else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 13:14:21
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 13:14:21
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:26:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'updated' (Site from DM).	Junlin Long (b) (4)	25 Mar 2021 13:55:35
DataPoint Un-verified.	(b) (4)	
	Junlin Long (b) (4)	25 Mar 2021 13:55:10
Signature has been broken.	(b) (4)	
	Junlin Long (b) (4)	25 Mar 2021 13:55:10
User entered 'REFLUX prevention' reason for change: Per Query Resolution	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
	(b) (4), (b) (6)	
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 06:02:54
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
	(b) (4)	
User entered 'REFLUX'	(b) (4), (b) (6)	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '6 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User entered '2'	System	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User entered '1'	System	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User entered '804 (804)'	System	18 Feb 2021 18:58:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: MIDODRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 19:00:53
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 19:00:53
Data point term sent to Coder	System	18 Feb 2021 19:00:14
User entered 'MIDODRINE'	(b) (4), (b) (6)	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'HYPOTENSION'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '5'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '1 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
User entered empty.	System	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
User entered empty.	System	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:56
User entered empty.	System	18 Feb 2021 18:59:18

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
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.	(b) (4) Coder Import (b) (4) (b) (4)	18 Feb 2021 19:16:53
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 19:16:53
Data point term sent to Coder	System	18 Feb 2021 19:01:17
User entered 'VANCOMYCIN'	(b) (4), (b) (6)	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Feb 2021 19:00:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 19:00:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 19:00:47
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 19:00:37
User entered empty.	(b) (4), (b) (6)	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'PNEUMONIA'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '750'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '26 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '3 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User entered '3'	System	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User entered '1'	System	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User entered '804 (804)'	System	18 Feb 2021 19:00:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
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: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:00:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 00:00:54
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	18 Feb 2021 19:02:18
User entered 'solumedrol'	(b) (4), (b) (6)	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '60'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '6 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
User entered '3'	System	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
User entered '1'	System	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:09
User entered '804 (804)'	System	18 Feb 2021 19:01:55

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:45:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:45:45
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 13:28:21
User entered 'oxygen'	(b) (4), (b) (6)	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'dyspnea, pneumonia'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'UNKNOWN'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'NRBM(Non rebreather mask)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	(b) (4)	19 Feb 2021 13:46:06
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	19 Feb 2021 13:46:06
User entered '6 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 13:46:06
User opened query 'Start Date is after Date of Death. Please review and reconcile.' (Site from System).	System	19 Feb 2021 13:27:56
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	19 Feb 2021 13:27:56
User entered '19 Feb 2021'	(b) (4), (b) (6)	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	19 Feb 2021 13:46:06
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	19 Feb 2021 13:27:56
User entered '4 Jan 2021'	(b) (4), (b) (6)	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
User entered empty.	System	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
User entered empty.	System	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:18
User entered empty.	System	19 Feb 2021 13:27:56

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: BILE AND LIVER THERAPY, ATC: LIVER THERAPY, LIPOTROPICS, ATC: LIVER THERAPY, PRODUCT: RIFAXIMIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:45:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:45:42
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 17:04:43
User entered 'RIFAXIMIN'	(b) (4), (b) (6)	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'SEPSIS'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '550'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '17 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
User entered '2'	System	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
User entered '1'	System	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:56
User entered '804 (804)'	System	19 Feb 2021 17:04:37

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
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)	28 Feb 2021 17:44:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Feb 2021 17:44:27
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 17:06:52
User entered 'VANCOMYCIN'	(b) (4), (b) (6)	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'SEPSIS'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '2'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
User entered '1'	System	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
User entered '1'	System	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:20
User entered '804 (804)'	System	19 Feb 2021 17:06:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: DAPTOMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 17:48:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 17:48:54
Data point term sent to Coder	System	19 Feb 2021 17:08:54
Data point term sent to Coder	System	19 Feb 2021 17:07:53
User entered 'DAPTOMYCIN'	(b) (4), (b) (6) (b) (4)	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 17:08:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 17:08:10
User entered 'SEPSIS' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 17:08:10
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 17:07:43
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '950'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 17:09:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 17:09:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 17:09:11
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 17:07:43
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
User entered '1'	System	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
User entered '1'	System	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:24
User entered '804 (804)'	System	19 Feb 2021 17:07:43

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: ANTIMYCOTICS FOR SYSTEMIC USE, ATC: OTHER ANTIMYCOTICS FOR SYSTEMIC USE, PRODUCT: MICAFUNGIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:50:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:50:58
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 17:11:02
User entered 'MICAFUNGIN'	(b) (4), (b) (6)	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'SEPSIS'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '100'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
User entered '1'	System	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
User entered '1'	System	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:31
User entered '804 (804)'	System	19 Feb 2021 17:10:20

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 14:03:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 14:03:45
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 17:12:04
User entered 'LASIX'	(b) (4), (b) (6)	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'METASTATIC HEPATOCELLULAR CARCINOMA'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '40'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '10 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '10 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
User entered '1'	System	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
User entered '1'	System	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:36
User entered '804 (804)'	System	19 Feb 2021 17:11:44

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 06:50:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 06:50:18
Data point term sent to Coder	System	25 Mar 2021 13:56:52
Coding entries removed.	Junlin Long (b) (4)	25 Mar 2021 13:56:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 17:15:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 17:15:51
Data point term sent to Coder	System	19 Feb 2021 17:14:06
User entered 'ONDANSETRON'	(b) (4), (b) (6)	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:26:09
DataPoint Un-verified.	Junlin Long (b) (4)	25 Mar 2021 13:56:42
Signature has been broken.	(b) (4) Junlin Long (b) (4)	25 Mar 2021 13:56:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Junlin Long (b) (4)	25 Mar 2021 13:56:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:13
User closed query 'Per CDM:RQ: Response provided as 'updated' However, required data has not been updated yet. Please review again the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. Else clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 09:19:10
Query 'Per CDM:RQ: Response provided as 'updated' Junlin Long However, required data has not been updated yet. Please review again the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. Else clarify' answered with 'Indication has been updated as "nausea prevention", so no MH or AE should be added.' (Site from DM).	(b) (4) (b) (4)	06 Apr 2021 15:49:26
User opened query 'Per CDM:RQ: Response provided as 'updated' However, required data has not been updated yet. Please review again the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. Else clarify' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 13:39:12
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)	26 Mar 2021 13:39:12
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:26:09
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	25 Mar 2021 13:56:50
DataPoint Un-verified.	Junlin Long (b) (4) (b) (4)	25 Mar 2021 13:56:42
Signature has been broken.	Junlin Long (b) (4) (b) (4)	25 Mar 2021 13:56:42

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
User entered 'NAUSEA prevention' reason for change: Per Query Resolution	Junlin Long (b) (4)	25 Mar 2021 13:56:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 11:13:49
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)	09 Mar 2021 06:03:27
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
	(b) (4)	
User entered 'NAUSEA'	(b) (4), (b) (6)	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '4'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 17:14:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 17:14:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 17:14:27
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 17:13:47
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User entered empty.	System	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User entered empty.	System	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:41
User entered empty.	System	19 Feb 2021 17:13:47

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN NOS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 17:05:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 17:05:53
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 17:16:08
User entered 'ALBUMIN 5%'	(b) (4), (b) (6)	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'SEPSIS'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '25'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '17 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '17 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User entered empty.	System	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User entered empty.	System	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:49
User entered empty.	System	19 Feb 2021 17:15:50

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
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) (b) (4)	31 Mar 2021 13:29:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:29:23
Data point term sent to Coder	System	25 Mar 2021 13:59:55
Coding entries removed.	Junlin Long (b) (4) (b) (4)	25 Mar 2021 13:59:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
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) (b) (4)	19 Feb 2021 17:54:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 17:54:54
Data point term sent to Coder	System	19 Feb 2021 17:18:10
User entered 'LORAZEPAM'	(b) (4), (b) (6)	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:13
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). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 12:47:04
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 'indication unknown (according to medical records)' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6) Junlin Long (b) (4) (b) (4)	25 Mar 2021 17:26:09 25 Mar 2021 13:59:19
Signature has been broken.	Junlin Long (b) (4) (b) (4)	25 Mar 2021 13:59:04
User entered 'unknown (according to medical records)' reason for change: Per Query Resolution DataPoint Verified.	Junlin Long (b) (4) (b) (4) (b) (4), (b) (6)	25 Mar 2021 13:59:04 24 Mar 2021 11:13:49
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). User signature succeeded.	(b) (4), (b) (6) Susanne Doblecki-Lewis	09 Mar 2021 06:03:38 19 Feb 2021 20:13:26
User entered 'AGITATION'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '1'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'IV PUSH'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
User entered empty.	System	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
User entered empty.	System	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:54
User entered empty.	System	19 Feb 2021 17:17:19

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: SODIUM BICARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:19:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:19:57
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 17:22:14
User entered 'SODIUM BICARBONATE'	(b) (4), (b) (6)	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'SEPSIS'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '1300'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
User entered '3'	System	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
User entered '1'	System	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:59
User entered '804 (804)'	System	19 Feb 2021 17:22:09

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM BICARBONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 10:08:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 10:08:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM BICARBONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:18:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:18:57
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 17:24:19
User entered 'sodium bicarbonate'	(b) (4), (b) (6)	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'sepsis'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '50'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'MeQ'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
User entered '1'	System	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
User entered '1'	System	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:09
User entered '804 (804)'	System	19 Feb 2021 17:23:33

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 18:00:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 18:00:53
Data point term sent to Coder	System	19 Feb 2021 17:29:25
User entered 'Dilaudid'	(b) (4), (b) (6)	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'metastatic hepatocellular carcinoma'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0.3'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'hour continuous'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User entered empty.	System	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User entered empty.	System	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User entered empty.	System	19 Feb 2021 17:29:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 17:05:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 17:05:53
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 17:31:27
User entered 'albumin 25%'	(b) (4), (b) (6)	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'sepsis'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '25'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'every 8 hours'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
User entered empty.	System	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
User entered empty.	System	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:21
User entered empty.	System	19 Feb 2021 17:31:07

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
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.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 17:46:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 17:46:58
Data point term sent to Coder	System	19 Feb 2021 17:33:29
User entered 'cefepime'	(b) (4), (b) (6)	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'sepsis'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '2'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'every 8 hours'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User entered empty.	System	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User entered empty.	System	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User entered empty.	System	19 Feb 2021 17:32:57

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 17:38:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 17:38:47
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 17:34:30
User entered 'flagyl'	(b) (4), (b) (6)	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'sepsis'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '500'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'every 8 hours'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '17 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
User entered empty.	System	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
User entered empty.	System	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:34
User entered empty.	System	19 Feb 2021 17:34:03

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: LACTULOSE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 12:27:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 12:27:13
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 17:35:38
User entered 'lactulose'	(b) (4), (b) (6)	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'sepsis'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '17 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
User entered '2'	System	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
User entered '1'	System	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:40
User entered '804 (804)'	System	19 Feb 2021 17:35:32

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: POSTERIOR PITUITARY LOBE HORMONES, ATC: VASOPRESSIN AND ANALOGUES, PRODUCT: VASOPRESSIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 17:18:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 17:18:30
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 17:37:40
User entered 'vasopressin'	(b) (4), (b) (6)	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'sepsis'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0.04'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'per min continuous'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
User entered empty.	System	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
User entered empty.	System	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:48
User entered empty.	System	19 Feb 2021 17:37:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
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) (b) (4)	20 Feb 2021 14:22:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 14:22:48
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 17:38:41
User entered 'meropenem'	(b) (4), (b) (6)	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'sepsis'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '1000'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'every 8 hours'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '17 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 17:38:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 17:38:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 17:38:33
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 17:38:22
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
User entered empty.	System	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
User entered empty.	System	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:55
User entered empty.	System	19 Feb 2021 17:38:22

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
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)	17 Mar 2021 11:39:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:39:41
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder System		19 Feb 2021 17:40:45
User entered 'norepinephrine'	(b) (4), (b) (6)	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'sepsis'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '5'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:13:49
Signature has been broken.	Junlin Long (b) (4)	09 Mar 2021 15:00:43
User entered 'ug (ug)' reason for change: Per Query Resolution	(b) (4) Junlin Long (b) (4)	09 Mar 2021 15:00:43
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:13:49
User closed query 'Per CDM: Please confirm if Units of MCG can be entered as UG in the Dose Unit field. Thank you' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 09:14:41
Query 'Per CDM: Please confirm if Units of MCG can be entered as UG in the Dose Unit field. Thank you' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	09 Mar 2021 15:00:47
Signature has been broken.	Junlin Long (b) (4) (b) (4)	09 Mar 2021 15:00:43
User entered empty; reason for change Per Query Resolution	Junlin Long (b) (4) (b) (4)	09 Mar 2021 15:00:43
User opened query 'Per CDM: Please confirm if Units of MCG can be entered as UG in the Dose Unit field. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 17:38:46
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mcg'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'MIN continuous' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 17:58:11
User entered 'min'	(b) (4), (b) (6)	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
User entered empty.	System	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
User entered empty.	System	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:10
User entered empty.	System	19 Feb 2021 17:39:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: HYPOTHALAMIC HORMONES, ATC: SOMATOSTATIN AND ANALOGUES, PRODUCT: OCTREOTIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:20:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:20:49
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 17:59:31
Data point term sent to Coder	System	19 Feb 2021 17:41:46
User entered 'ocetreotide'	(b) (4), (b) (6) (b) (4), (b) (6)	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'sepsis'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '50'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:13:49
Signature has been broken.	Junlin Long (b) (4)	09 Mar 2021 15:00:58
User entered 'ug (ug)' reason for change: Per Query Resolution	(b) (4) Junlin Long (b) (4)	09 Mar 2021 15:00:58
User signature succeeded.	(b) (4) Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:13:49
User closed query 'Per CDM: Please confirm if Units of MCG can be entered as UG in the Dose Unit field. Thank you' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 09:15:02
Query 'Per CDM: Please confirm if Units of MCG can be entered as UG in the Dose Unit field. Thank you' answered with 'updated' (Site from DM).	Junlin Long (b) (4) (b) (4)	09 Mar 2021 15:01:04
Signature has been broken.	Junlin Long (b) (4) (b) (4)	09 Mar 2021 15:00:58
User entered empty; reason for change Per Query Resolution	Junlin Long (b) (4) (b) (4)	09 Mar 2021 15:00:58
User opened query 'Per CDM: Please confirm if Units of MCG can be entered as UG in the Dose Unit field. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 17:39:10
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mcg'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'hour continuous'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 17:58:52
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '17 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 17:41:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 17:41:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 17:41:40
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 17:41:24
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
User entered empty.	System	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
User entered empty.	System	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:13
User entered empty.	System	19 Feb 2021 17:41:24

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
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, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 10:17:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 10:17:37
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 17:43:50
User entered 'pepcid'	(b) (4), (b) (6)	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
User entered '2'	System	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
User entered '1'	System	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:19
User entered '804 (804)'	System	19 Feb 2021 17:43:10

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 14:16:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 14:16:44
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 17:44:54
User entered 'Lovenox'	(b) (4), (b) (6)	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'prevention of blood clots'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '40'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 17:44:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 17:44:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 17:44:41
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 17:44:34
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 18:01:07
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
User entered '1'	System	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
User entered '1'	System	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:54:23
User entered '804 (804)'	System	19 Feb 2021 17:44:34

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: GLYCOPYRRONIUM, PRODUCTSYNONYM: GLYCOPYRROLATE [GLYCOPYRRONIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:26:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:26:04
Data point term sent to Coder Coding entries removed.	System Junlin Long (b) (4)	25 Mar 2021 14:02:03 25 Mar 2021 14:01:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: GLYCOPYRRONIUM, PRODUCTSYNONYM: GLYCOPYRROLATE [GLYCOPYRRONIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 12:27:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 12:27:55
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder User entered 'glycopyrrolate'	System (b) (4), (b) (6)	19 Feb 2021 17:47:02 19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	09 Apr 2021 19:56:13
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, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:00:23
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'indication unknown (according to medical records)' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6) Junlin Long (b) (4) (b) (4)	25 Mar 2021 17:26:09 25 Mar 2021 14:01:13
Signature has been broken.	Junlin Long (b) (4) (b) (4)	25 Mar 2021 14:01:04
User entered 'unknown (according to medical records)' reason for change: Per Query Resolution DataPoint Verified.	Junlin Long (b) (4) (b) (4) (b) (4), (b) (6)	25 Mar 2021 14:01:04 24 Mar 2021 11:13:49
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, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Susanne Doblecki-Lewis	09 Mar 2021 06:03:58 19 Feb 2021 20:13:26
User entered 'secretions'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0.2'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'every 6 hours'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 17:46:38

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: ANTIBIOTICS, PRODUCT: NYSTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:26:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:26:36
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder	System	19 Feb 2021 18:03:08
User entered 'NYSTATIN topical' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 18:02:31
Data point term sent to Coder	System	19 Feb 2021 17:48:09
User entered 'nystatin'	(b) (4), (b) (6)	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '1'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'application'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Topical (TOPICAL)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Feb 2021 17:47:51

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
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;SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL;IPRATROPIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 17:06:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 17:06:54
User signature succeeded.	Susanne Doblecki-Lewis (b) (4)	19 Feb 2021 20:13:26
Data point term sent to Coder System	(b) (4), (b) (6)	19 Feb 2021 17:50:11
User entered 'albuterol-ipratropium'	(b) (4), (b) (6)	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '1'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'inhalation'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'every 6 hours'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'nebulizer'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '20 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:49
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 10 Jun 2021 09:14:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 17:49:58

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:14:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:46:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:24
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Feb 2021 17:33:47
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	02 Feb 2021 15:21:23
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	02 Feb 2021 15:20:04

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:34:26

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'x-ray'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:34:26

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:34:26

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:34:26

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:34:58

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'EKG'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:34:58

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:34:58

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:34:58

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:35:19

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:35:19

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:35:19

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:35:19

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '09 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:35:41

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:35:41

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:35:41

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:56
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:35:41

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:01

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:01

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:01

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:32:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:01

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:14:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:32

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:32

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:32

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:32

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:56

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:56

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:56

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:26
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:36:56

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:14:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:37:15

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:37:15

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:37:15

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:37:15

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:37:30

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:37:30

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:37:30

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:37:30

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '19 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:37:46

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:37:46

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:37:46

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:37:46

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:38:17

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:38:17

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:38:17

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:38:17

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:38:39

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:38:39

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:38:39

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:38:39

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '24 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:38:58

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:38:58

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:38:58

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:33:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:38:58

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '25 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:39:13

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:39:13

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:39:13

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:01
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:39:13

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '26 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:39:36

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:50:27
User entered 'CHEST X-RAYD'	(b) (4), (b) (6)	18 Feb 2021 17:39:36

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:39:36

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:39:36

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:40:33

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:40:33

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:40:33

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (16)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:11
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:40:33

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:40:52

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:40:52

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:40:52

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (17)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:40:52

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '31 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:41:09

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:41:09

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:41:09

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (18)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:23
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:41:09

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 09:14:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	18 Feb 2021 17:41:37
User closed query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	18 Feb 2021 17:41:37
User closed query 'Procedure Date is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	18 Feb 2021 17:41:37
User entered '01 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 17:41:37
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	18 Feb 2021 17:41:24
User opened query 'Procedure Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	18 Feb 2021 17:41:24
User opened query 'Procedure Date is after Date of Death. Please review and provide any needed correction.' (Site from System).	System	18 Feb 2021 17:41:24
User entered '01 Dec 2021'	(b) (4), (b) (6)	18 Feb 2021 17:41:24

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:41:24

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:41:24

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (19)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:41:24

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '03 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:42:01

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:42:01

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:42:01

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (20)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:42:01

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:42:20

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:42:20

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:42:20

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (21)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:34
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:42:20

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:43:12

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'ECHOCARDIOGRAM'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:43:12

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:43:12

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (22)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:43:12

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '31 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:43:34

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'ECHOCARDIOGRAM'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:43:34

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:43:34

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (23)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:43:34

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '27 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:44:08

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CTA CHEST'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:44:08

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:44:08

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (24)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:50
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:44:08

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 10 Jun 2021 09:14:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:44:37

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'ABDOMINAL ULTRASOUND'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:44:37

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:44:37

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (25)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:44:37

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:12

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CT GUIDED LIVER BIOPSY'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:12

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:12

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (26)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:34:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:45:12

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 10 Jun 2021 09:14:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:47:09

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'RIGHT PLEURAL DRAIN PLACEMENT UNDER U/S GUIDANCE'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:47:09

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:47:09

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (27)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:47:09

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 10 Jun 2021 09:14:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:47:30

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'RIGHT THORACENTESIS'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:47:30

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:47:30

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (28)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:09
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:47:30

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '09 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:48:11

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CT ABD/PELVIS W/WO CONTRAST'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:48:11

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:48:11

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (29)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:13
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:48:11

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '26 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:48:46

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'VENOUS DUPLEX ULTRASOUND UE RIGHT'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:48:46

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:48:46

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (30)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:16
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 17:48:46

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:03:54

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CT CHEST, ABDOMEN, PELVIS'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:03:54

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:03:54

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (31)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:36
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:03:54

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (32)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '17 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:04:27

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (32)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CT ABDOMEN PELVIS W/WO CONTRAST'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:04:27

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (32)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:04:27

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (32)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:04:27

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (33)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:04:53

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (33)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'ABDOMINAL ULTRASOUND'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:04:53

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (33)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:04:53

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (33)

Generated On: 10 Jun 2021 09:14:19

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:44
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:04:53

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (34)

Generated On: 10 Jun 2021 09:14:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:05:11

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (34)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:05:11

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (34)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:05:11

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (34)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:05:11

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (35)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:05:29

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (35)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CHEST X-RAY'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:05:29

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (35)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:05:29

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (35)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:05:29

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (36)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:06:07

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (36)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'CENTRAL VENOUS LANE PLACEMENT'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:06:07

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (36)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:06:07

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (36)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:35:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:06:07

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (37)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:06:28

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (37)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'ECHOCARDIOGRAM'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:06:28

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (37)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:06:28

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (37)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:00
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 13:06:28

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (38)

Generated On: 10 Jun 2021 09:14:19

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:13:37
User entered '06 Dec 2020'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:37:54

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (38)

Generated On: 10 Jun 2021 09:14:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:13:37
User entered 'CTA CHEST'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:37:54

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (38)

Generated On: 10 Jun 2021 09:14:19

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:13:37
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:37:54

US3622169

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (38)

Generated On: 10 Jun 2021 09:14:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:36:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:14:37
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:13:37
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:37:54

US3622169

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:14:19

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:57:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:05:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:19:35
User closed query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	28 Jan 2021 18:31:39
User entered '21 Jan 2021' reason for change: Per Query Resolution	Junlin Long (b) (4) (b) (4)	28 Jan 2021 18:31:39
User opened query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	28 Jan 2021 18:31:14
User entered '25 Jan 2021'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 18:24:44

US3622169

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:14:19

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:57:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:05:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:19:35
User entered 'Death (DEATH)'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 18:24:44

US3622169

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:14:19

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)	29 Apr 2021 06:57:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:05:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:19:35
User entered empty.	Junlin Long (b) (4) (b) (4)	25 Jan 2021 18:24:44

US3622169

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:14:19

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:57:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:05:21
User closed query 'Per CDM:Reason for death is selected as AE, however kindly consider to provide the AE# log line number for which death has occurred. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 05:09:34
Query 'Per CDM:Reason for death is selected as AE, however kindly consider to provide the AE# log line number for which death has occurred. Thank you. ' answered with 'please refer to ae line 5.' (Site from DM).	Junlin Long (b) (4) (b) (4)	02 Feb 2021 17:04:12
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 15:19:35
User opened query 'Per CDM:Reason for death is selected as AE, however kindly consider to provide the AE# log line number for which death has occurred. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 13:59:59
User entered 'Adverse event (ADVERSE EVENT)' reason for change: New Information	Junlin Long (b) (4) (b) (4)	28 Jan 2021 18:31:14
User entered 'Unknown (UNKNOWN)'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 18:24:44

US3622169

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:14:19

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:57:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:05:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:19:35
User entered empty.	Junlin Long (b) (4) (b) (4)	25 Jan 2021 18:24:44

US3622169

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:14:19

Date of death (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:57:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:05:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:19:35
User closed query 'Reason for discontinuation is Death, however date of death is missing. Please provide.' (Site from System).	System	28 Jan 2021 18:31:14
User entered '21 Jan 2021' reason for change: Per Query Resolution	Junlin Long (b) (4)	28 Jan 2021 18:31:14
Comment added 'date of death unknown'.	(b) (4) Junlin Long (b) (4)	25 Jan 2021 18:25:19
User opened query 'Reason for discontinuation is Death, however date of death is missing. Please provide.' (Site from System).	(b) (4) System	25 Jan 2021 18:24:44
User entered empty.	Junlin Long (b) (4)	25 Jan 2021 18:24:44
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:14:19

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:57:35
User signature succeeded.	Susanne Doblecki-Lewis	12 Feb 2021 14:05:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:19:35
User entered 'Unknown (UNK)'	Junlin Long (b) (4) (b) (4)	25 Jan 2021 18:24:44

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'USA-US085-2020-MRNA-1273-P301000004'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:24:52
Un-reviewed for Safety.	System	22 Feb 2021 14:19:06
DataPoint Un-verified.	System	22 Feb 2021 14:19:06
Signature has been broken.	System	22 Feb 2021 14:19:06
User entered 'Yes (Y)'	System	22 Feb 2021 14:19:06
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Susanne'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Doblecki-Lewis'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '1120 NW 14th Street'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Miami'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'FL'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '33136'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 00:24:46
User entered 'US'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	10 Mar 2021 15:28:07
User entered '7'	System	23 Feb 2021 14:08:04
Signature has been broken.	System	22 Feb 2021 14:25:05
User entered '6'	System	22 Feb 2021 14:25:05
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
	(b) (4)	
User entered '5'	System	19 Feb 2021 14:44:18
Signature has been broken.	System	18 Feb 2021 20:29:57
User entered '4'	System	18 Feb 2021 20:29:57
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 15:25:10
User entered '3'	System	27 Jan 2021 15:25:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
	(b) (4)	
User entered '2'	System	08 Dec 2020 00:24:58
User entered '1'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'USA-US085-2020-MRNA-1273-P301000004'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:24:52
Un-reviewed for Safety.	System	22 Feb 2021 14:19:06
DataPoint Un-verified.	System	22 Feb 2021 14:19:06
Signature has been broken.	System	22 Feb 2021 14:19:06
User entered 'Yes (Y)'	System	22 Feb 2021 14:19:06
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Susanne'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Doblecki-Lewis'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '1120 NW 14th Street'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Miami'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'FL'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '33136'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 00:24:46
User entered 'US'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	10 Mar 2021 15:28:07
User entered '7'	System	23 Feb 2021 14:08:04
Signature has been broken.	System	22 Feb 2021 14:25:05
User entered '6'	System	22 Feb 2021 14:25:05
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
	(b) (4)	
User entered '5'	System	19 Feb 2021 14:44:18
Signature has been broken.	System	18 Feb 2021 20:29:57
User entered '4'	System	18 Feb 2021 20:29:57
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 15:25:10
User entered '3'	System	27 Jan 2021 15:25:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
	(b) (4)	
User entered '2'	System	08 Dec 2020 00:24:58
User entered '1'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:14:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered '07/Dec/2020 12:27'	(b) (4) System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:14:19

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)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 00:24:46
User entered '1'	(b) (4), (b) (6)	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'USA-US085-2020-MRNA-1273-P301000004'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:24:52
Un-reviewed for Safety.	System	22 Feb 2021 14:19:06
DataPoint Un-verified.	System	22 Feb 2021 14:19:06
Signature has been broken.	System	22 Feb 2021 14:19:06
User entered 'Yes (Y)'	System	22 Feb 2021 14:19:06
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Susanne'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Doblecki-Lewis'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '1120 NW 14th Street'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Miami'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'FL'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '33136'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 00:24:46
User entered 'US'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	10 Mar 2021 15:28:07
User entered '7'	System	23 Feb 2021 14:08:04
Signature has been broken.	System	22 Feb 2021 14:25:05
User entered '6'	System	22 Feb 2021 14:25:05
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
	(b) (4)	
User entered '5'	System	19 Feb 2021 14:44:18
Signature has been broken.	System	18 Feb 2021 20:29:57
User entered '4'	System	18 Feb 2021 20:29:57
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 15:25:10
User entered '3'	System	27 Jan 2021 15:25:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
	(b) (4)	
User entered '2'	System	08 Dec 2020 00:24:58
User entered '1'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:14:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered '08/Dec/2020 00:24'	(b) (4) System	08 Dec 2020 00:24:58

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:14:19

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)
Reviewed for Safety.	(b) (4), (b) (6)	27 Jan 2021 15:24:54
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered '1'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 00:24:58

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'USA-US085-2020-MRNA-1273-P301000004'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:24:52
Un-reviewed for Safety.	System	22 Feb 2021 14:19:06
DataPoint Un-verified.	System	22 Feb 2021 14:19:06
Signature has been broken.	System	22 Feb 2021 14:19:06
User entered 'Yes (Y)'	System	22 Feb 2021 14:19:06
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Susanne'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Doblecki-Lewis'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '1120 NW 14th Street'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Miami'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'FL'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '33136'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 00:24:46
User entered 'US'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	10 Mar 2021 15:28:07
User entered '7'	System	23 Feb 2021 14:08:04
Signature has been broken.	System	22 Feb 2021 14:25:05
User entered '6'	System	22 Feb 2021 14:25:05
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
	(b) (4)	
User entered '5'	System	19 Feb 2021 14:44:18
Signature has been broken.	System	18 Feb 2021 20:29:57
User entered '4'	System	18 Feb 2021 20:29:57
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 15:25:10
User entered '3'	System	27 Jan 2021 15:25:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
	(b) (4)	
User entered '2'	System	08 Dec 2020 00:24:58
User entered '1'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:14:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
User entered '27/Jan/2021 10:25'	(b) (4) System	27 Jan 2021 15:25:10

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:14:19

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)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:29:41
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
User entered '1'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:10

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'USA-US085-2020-MRNA-1273-P301000004'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:24:52
Un-reviewed for Safety.	System	22 Feb 2021 14:19:06
DataPoint Un-verified.	System	22 Feb 2021 14:19:06
Signature has been broken.	System	22 Feb 2021 14:19:06
User entered 'Yes (Y)'	System	22 Feb 2021 14:19:06
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Susanne'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Doblecki-Lewis'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '1120 NW 14th Street'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Miami'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'FL'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '33136'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 00:24:46
User entered 'US'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	10 Mar 2021 15:28:07
User entered '7'	System	23 Feb 2021 14:08:04
Signature has been broken.	System	22 Feb 2021 14:25:05
User entered '6'	System	22 Feb 2021 14:25:05
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
	(b) (4)	
User entered '5'	System	19 Feb 2021 14:44:18
Signature has been broken.	System	18 Feb 2021 20:29:57
User entered '4'	System	18 Feb 2021 20:29:57
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 15:25:10
User entered '3'	System	27 Jan 2021 15:25:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
	(b) (4)	
User entered '2'	System	08 Dec 2020 00:24:58
User entered '1'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:14:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '18/Feb/2021 15:29'	(b) (4) System	18 Feb 2021 20:29:57

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:14:19

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)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 14:43:56
User entered '1'	(b) (4), (b) (6)	18 Feb 2021 20:29:57

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'USA-US085-2020-MRNA-1273-P301000004'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:24:52
Un-reviewed for Safety.	System	22 Feb 2021 14:19:06
DataPoint Un-verified.	System	22 Feb 2021 14:19:06
Signature has been broken.	System	22 Feb 2021 14:19:06
User entered 'Yes (Y)'	System	22 Feb 2021 14:19:06
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Susanne'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Doblecki-Lewis'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '1120 NW 14th Street'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Miami'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'FL'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '33136'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 00:24:46
User entered 'US'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	10 Mar 2021 15:28:07
User entered '7'	System	23 Feb 2021 14:08:04
Signature has been broken.	System	22 Feb 2021 14:25:05
User entered '6'	System	22 Feb 2021 14:25:05
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
	(b) (4)	
User entered '5'	System	19 Feb 2021 14:44:18
Signature has been broken.	System	18 Feb 2021 20:29:57
User entered '4'	System	18 Feb 2021 20:29:57
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 15:25:10
User entered '3'	System	27 Jan 2021 15:25:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
	(b) (4)	
User entered '2'	System	08 Dec 2020 00:24:58
User entered '1'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:14:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '19/Feb/2021 09:44'	(b) (4) System	19 Feb 2021 14:44:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:14:19

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)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 14:24:52
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
User entered '1'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 14:44:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'USA-US085-2020-MRNA-1273-P301000004'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:24:52
Un-reviewed for Safety.	System	22 Feb 2021 14:19:06
DataPoint Un-verified.	System	22 Feb 2021 14:19:06
Signature has been broken.	System	22 Feb 2021 14:19:06
User entered 'Yes (Y)'	System	22 Feb 2021 14:19:06
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Susanne'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Doblecki-Lewis'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '1120 NW 14th Street'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Miami'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'FL'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '33136'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 00:24:46
User entered 'US'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	10 Mar 2021 15:28:07
User entered '7'	System	23 Feb 2021 14:08:04
Signature has been broken.	System	22 Feb 2021 14:25:05
User entered '6'	System	22 Feb 2021 14:25:05
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
	(b) (4)	
User entered '5'	System	19 Feb 2021 14:44:18
Signature has been broken.	System	18 Feb 2021 20:29:57
User entered '4'	System	18 Feb 2021 20:29:57
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 15:25:10
User entered '3'	System	27 Jan 2021 15:25:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
	(b) (4)	
User entered '2'	System	08 Dec 2020 00:24:58
User entered '1'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:14:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:48
User entered '22/Feb/2021 14:25'	(b) (4) System	22 Feb 2021 14:25:05

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:14:19

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)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:48
User entered '1'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:25:05

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'USA-US085-2020-MRNA-1273-P301000004'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:24:52
Un-reviewed for Safety.	System	22 Feb 2021 14:19:06
DataPoint Un-verified.	System	22 Feb 2021 14:19:06
Signature has been broken.	System	22 Feb 2021 14:19:06
User entered 'Yes (Y)'	System	22 Feb 2021 14:19:06
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Susanne'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Doblecki-Lewis'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '1120 NW 14th Street'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Miami'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'FL'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '33136'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 00:24:46
User entered 'US'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	10 Mar 2021 15:28:07
User entered '7'	System	23 Feb 2021 14:08:04
Signature has been broken.	System	22 Feb 2021 14:25:05
User entered '6'	System	22 Feb 2021 14:25:05
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
	(b) (4)	
User entered '5'	System	19 Feb 2021 14:44:18
Signature has been broken.	System	18 Feb 2021 20:29:57
User entered '4'	System	18 Feb 2021 20:29:57
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 15:25:10
User entered '3'	System	27 Jan 2021 15:25:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
	(b) (4)	
User entered '2'	System	08 Dec 2020 00:24:58
User entered '1'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:14:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:48
User entered '23/Feb/2021 09:08'	(b) (4) System	23 Feb 2021 14:08:04

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:14:19

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)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:48
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:08:04
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 14:04:06

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'USA-US085-2020-MRNA-1273-P301000004'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	05 Mar 2021 21:56:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:24:52
Un-reviewed for Safety.	System	22 Feb 2021 14:19:06
DataPoint Un-verified.	System	22 Feb 2021 14:19:06
Signature has been broken.	System	22 Feb 2021 14:19:06
User entered 'Yes (Y)'	System	22 Feb 2021 14:19:06
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Yes (Y)'	System	07 Dec 2020 20:22:16
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'No (N)'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Susanne'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Doblecki-Lewis'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '1120 NW 14th Street'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'Miami'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered 'FL'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 20:27:01
User entered '33136'	System	07 Dec 2020 20:20:22

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:20:06
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 00:24:46
User entered 'US'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	10 Mar 2021 15:28:07
User entered '7'	System	23 Feb 2021 14:08:04
Signature has been broken.	System	22 Feb 2021 14:25:05
User entered '6'	System	22 Feb 2021 14:25:05
User signature succeeded.	Susanne Doblecki-Lewis	19 Feb 2021 20:13:26
	(b) (4)	
User entered '5'	System	19 Feb 2021 14:44:18
Signature has been broken.	System	18 Feb 2021 20:29:57
User entered '4'	System	18 Feb 2021 20:29:57
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
	(b) (4)	
Signature has been broken.	System	27 Jan 2021 15:25:10
User entered '3'	System	27 Jan 2021 15:25:10
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
	(b) (4)	
User entered '2'	System	08 Dec 2020 00:24:58
User entered '1'	System	07 Dec 2020 20:27:18

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:14:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:13:37
User entered '10/Mar/2021 07:27'	(b) (4) System	10 Mar 2021 15:28:07

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:14:19

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)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:12:26
User signature succeeded.	Susanne Doblecki-Lewis	12 Mar 2021 13:13:37
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 15:28:07

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered	(b) (4)	08 Dec 2020 00:22:40
'USA-US085-2020-MRNA-1273-P301000005'	System	

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'No (N)'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'No (N)'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'No (N)'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'No (N)'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'No (N)'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'No (N)'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'No (N)'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'Susanne'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'Doblecki-Lewis'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered '1120 NW 14th Street'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'Miami'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'FL'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered '33136'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'US'	(b) (4) System	08 Dec 2020 00:24:58

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered	(b) (4)	08 Dec 2020 00:22:40
'USA-US085-2020-MRNA-1273-P301000005'	System	

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'No (N)'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'No (N)'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'No (N)'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'No (N)'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'No (N)'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'No (N)'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'No (N)'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'Susanne'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'Doblecki-Lewis'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered '1120 NW 14th Street'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'Miami'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'FL'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered '33136'	(b) (4) System	08 Dec 2020 00:22:40

US3622169

Folder: SAE USA-US085-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:19:44
User signature succeeded.	Susanne Doblecki-Lewis	14 Jan 2021 15:06:31
User entered 'US'	(b) (4) System	08 Dec 2020 00:24:58

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'USA-US085-2021-MRNA-1273-P301000008'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'Yes (Y)'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'Yes (Y)'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'No (N)'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'Yes (Y)'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'No (N)'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'No (N)'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'No (N)'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'Susanne'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'Doblecki-Lewis'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered '1120 NW 14th Street'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'Miami'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'FL'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered '33136'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'US'	System	27 Jan 2021 15:25:10

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
	(b) (4)	
User entered '1'	System	27 Jan 2021 15:25:51

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'USA-US085-2021-MRNA-1273-P301000008'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'Yes (Y)'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'Yes (Y)'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'No (N)'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'Yes (Y)'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'No (N)'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'No (N)'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'No (N)'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'Susanne'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'Doblecki-Lewis'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered '1120 NW 14th Street'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'Miami'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'FL'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered '33136'	System	27 Jan 2021 15:24:30

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:36
User entered 'US'	System	27 Jan 2021 15:25:10

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:14:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
	(b) (4)	
User entered '1'	System	27 Jan 2021 15:25:51

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:14:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
User entered '27/Jan/2021 10:25'	(b) (4) System	27 Jan 2021 15:25:51

US3622169

Folder: SAE USA-US085-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:14:19

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)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 11:13:00
User signature succeeded.	Susanne Doblecki-Lewis	28 Jan 2021 15:09:46
User entered '1'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:25:51