

US3242231 (Prod: Clinical Research Atlanta - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:11:06

All time stamps listed in this document are displayed in GMT

US3242231

Form: Participant Creation

Data signed: (b) (4) 10 Feb 2021 20:11:44

Generated On: 09 Jun 2021 16:11:06

Participant ID

US3242231

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

US3242231

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3242231

Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Date of Birth (MMM yyyy)	(b) (6) 1943
Age	76
Age Units	YEARS
Age (Derived)	76
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Feb 2021 20:12:27

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Date of Informed Consent (<i>dd MMM yyyy</i>)	27 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3242231

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Did the participant meet all eligibility criteria?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1976
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1976
Start Year (derived)	1976
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242231

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Condition	ENDOMETRIOSIS
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1975
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	JAN 1975
Stop Year (derived)	1975

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Condition	FATTY LIVER
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242231

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1975
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	JAN 1975
Stop Year (derived)	1975

US3242231

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Condition	DRUG ALLERGY-IBUPROFEN
Start date (dd MMM yyyy)	1 JAN 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

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

US3242231

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	24 OCT 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Condition	CHRONIC KIDNEY DISEASE STAGE 3
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3242231

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Condition	THORACIC AORTIC ANEURYSM WITHOUT RUPTURE
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3242231

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Condition	OBESITY
Start date (dd MMM yyyy)	24 OCT 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3242231

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	09:44 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 09:44
Height (xxx.x)	62 in
Weight (xxx.x)	174 lb
BMI (xxx.x)	31.89156 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242231

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Date of assessment (dd MMM yyyy) 27 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☒
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1975

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

RETIRED, SHOPS IN
COMMUNITY SEVERAL TIMES
A WEEK

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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EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Feb 2021 20:12:27

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

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

Visit date (dd MMM yyyy)	27 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3242231

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 188735

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 ☒

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

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) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	10:09 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 10:09
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	16:23 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 16:23
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3242231

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3242231

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 27 AUG 2020

What was the treatment time? (00:00-23:59) 15:53 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 15:53

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) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 27 AUG 2020

Collection time (00:00-23:59) 10:44 (24 HR)

Collection date and time (derived) 27 AUG 2020 10:44

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:39	27 AUG 2020 10:39
Nasopharyngeal Swab 2	No		

US3242231

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 16:33

PC Open Date & Time

27 AUG 2020 16:13

PC Close Date & Time

27 AUG 2020 18:43

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.8 °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	27 AUG 2020 20:51
PC Open Date & Time	27 AUG 2020 19:38
PC Close Date & Time	28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 20:49

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 07:50

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 08:42

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

31 AUG 2020 21:28

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

01 SEP 2020 22:05

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 19:28

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 16:34

PC Open Date & Time

27 AUG 2020 16:13

PC Close Date & Time

27 AUG 2020 18:43

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 20:52

PC Open Date & Time

27 AUG 2020 19:38

PC Close Date & Time

28 AUG 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 20:50

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 07:50

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 08:42

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 21:28

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 22:05

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 19:29

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 16:35
PC Open Date & Time	27 AUG 2020 16:13
PC Close Date & Time	27 AUG 2020 18:43

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 20:53
PC Open Date & Time	27 AUG 2020 19:38
PC Close Date & Time	28 AUG 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 20:52
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 07:51
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 3752

EAB) (1725)

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 08:43
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 3752

EAB) (1725)

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 21:30
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 3752

EAB) (1725)

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 22:06
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

64 of 3752

EAB) (1725)

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 19:29
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3242231

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3242231

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242231

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 20:11:46

Generated On: 09 Jun 2021 16:11:06

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3242231

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 20:11:46

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242231

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 20:11:46

Generated On: 09 Jun 2021 16:11:06

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3242231

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 20:11:46

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242231

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	08:36 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 08:36
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	10:19 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 10:19
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3242231

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3242231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 25 SEP 2020

What was the treatment time? (00:00-23:59) 09:46 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 09:46

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

US3242231

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 25 SEP 2020

Collection time (00:00-23:59) 09:13 (24 HR)

Collection date and time (derived) 25 SEP 2020 09:13

US3242231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:10	25 SEP 2020 09:10
Nasopharyngeal Swab 2	No		

US3242231

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 10:22

PC Open Date & Time

25 SEP 2020 10:06

PC Close Date & Time

25 SEP 2020 12:36

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 25 SEP 2020 23:47

PC Open Date & Time 25 SEP 2020 13:31

PC Close Date & Time 26 SEP 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 17:15

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

27 SEP 2020 21:35

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

28 SEP 2020 18:50

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 17:31

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 6

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 21:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 20:36

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 10:22

PC Open Date & Time

25 SEP 2020 10:06

PC Close Date & Time

25 SEP 2020 12:36

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 23:50

PC Open Date & Time

25 SEP 2020 13:31

PC Close Date & Time

26 SEP 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 17:16

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 21:36

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 18:51

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 17:32

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 21:04

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 20:37

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 10:23
PC Open Date & Time	25 SEP 2020 10:06
PC Close Date & Time	25 SEP 2020 12:36

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 23:51
PC Open Date & Time	25 SEP 2020 13:31
PC Close Date & Time	26 SEP 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 17:18
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 21:37
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 18:52
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 17:33
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 21:05
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 20:37
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3242231

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 20:11:46

Generated On: 09 Jun 2021 16:11:06

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3242231

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 20:11:46

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242231

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 20:11:46

Generated On: 09 Jun 2021 16:11:06

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3242231

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 20:11:46

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242231

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3242231

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242231

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	22 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:02 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 09:02
Temperature (<i>xxx.x</i>)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3242231

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3242231

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

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

Collection date (dd MMM yyyy)	22 OCT 2020
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Collection time (00:00-23:59)	09:30 (24 HR)
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Collection date and time (derived)	22 OCT 2020 09:30
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US3242231

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 20:12:28

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 OCT 2020 07:45:40
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 15:51:02

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 11:31:26
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 22:24:52
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

Date and time of submission

08 DEC 2020 17:42:45

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

Date and time of submission

15 DEC 2020 08:33:13

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

21 DEC 2020 14:34:39

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

29 DEC 2020 08:26:00

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

Date and time of submission

04 JAN 2021 22:11:09

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 138

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

No ☒

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 09:22:01

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 145

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

No ☒

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

18 JAN 2021 22:09:47

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 152

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

No ☒

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

27 JAN 2021 15:33:28

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 159

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

No ☒

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 FEB 2021 19:04:34

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 14:57:56
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 08:22:31
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 21:22:57
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 07:55:12

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 MAR 2021 20:12:57
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 MAR 2021 18:03:16

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 17:26:58

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 10:40:48

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 20:01:34

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 07:00:29

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 250

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 MAY 2021 22:51:00

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 257

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 278

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 JUN 2021 00:01
Patient Cloud Close Date & Time	23 JUN 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 306

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 313

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 327

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 355

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	14 AUG 2021 00:01
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 362

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 369

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 376

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 383

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2021 00:01
Patient Cloud Close Date & Time	29 SEP 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	13 NOV 2021 00:01
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Patient Cloud Close Date & Time	17 NOV 2021 23:59
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US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 453

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 JAN 2022 00:01
Patient Cloud Close Date & Time	05 JAN 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 509

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 523

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 537

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 FEB 2022 00:01
Patient Cloud Close Date & Time	23 FEB 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 551

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 558

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 565

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 MAR 2022 00:01
Patient Cloud Close Date & Time	16 MAR 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 572

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 579

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 586

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 593
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 649

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 663

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 698

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 726

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2022 00:01
Patient Cloud Close Date & Time	24 AUG 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 733

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2022 00:01
Patient Cloud Close Date & Time	21 SEP 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 775

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

DAY 789

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 ☐

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3242231

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:11:06

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		11 MAR 2021 17:05:50

US3242231

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3242231

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 20:12:27

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242231

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 20:11:46

Generated On: 09 Jun 2021 16:11:06

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3242231

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 20:11:46

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242231

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 10 Feb 2021 20:11:46

Generated On: 09 Jun 2021 16:11:06

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3242231

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 10 Feb 2021 20:11:46

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242231

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Mar 2021 22:05:50

Generated On: 09 Jun 2021 16:11:06

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3242231

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Mar 2021 22:05:50

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242231

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 18:15:22

Generated On: 09 Jun 2021 16:11:06

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

Visit date (dd MMM yyyy)	24 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:57:12

Generated On: 09 Jun 2021 16:11:06

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3242231

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 18:15:22

Generated On: 09 Jun 2021 16:11:06

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3242231

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 18:15:22

Generated On: 09 Jun 2021 16:11:06

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 24 MAR 2021

Collection time (00:00-23:59) 12:05 (24 HR)

Collection date and time (derived) 24 MAR 2021 12:05

US3242231

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 18:15:22

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242231

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:37:29

Generated On: 09 Jun 2021 16:11:06

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3242231

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:37:29

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3242231

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3242231

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3242231

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:11:06

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

US3242231

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:11:06

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3242231

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

Form: Visit Date

Data signed: (b) (4) 10 Feb 2021 20:11:46

Generated On: 09 Jun 2021 16:11:06

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 19 JAN 2021

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

Folder OID UNBLND_DECIDE

US3242231

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 16:05:31

Generated On: 09 Jun 2021 16:11:06

Date of updated informed consent (dd MMM yyyy) 19 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 19 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3242231

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Feb 2021 20:11:46

Generated On: 09 Jun 2021 16:11:06

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 19 JAN 2021

Collection time (00:00-23:59) 11:12 (24 HR)

Collection date and time (derived) 19 JAN 2021 11:12

US3242231

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 10 Feb 2021 20:11:45

Generated On: 09 Jun 2021 16:11:06

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	10:43
Collection Date and Time (derived)	19 JAN 2021 10:43

US3242231

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 10 Feb 2021 20:11:45

Generated On: 09 Jun 2021 16:11:06

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

AEID

Adverse event

WORSENING OF
HYPERLIPIDEMIA

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)

1 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

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

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

AEID	USA-US067-2020-MRNA-1273-P30 1000003
Adverse event	UNCONTROLLED HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	8 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	09 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	336 of 3752

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

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

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

SUBJECT WENT TO
CARDIOLOGIST TO FOLLOW UP
FOR YEARLY APPOINTMENT
TO FOLLOW UP ON AORTIC
ANEURYSM. ECHO WAS DONE
AND BP WAS 177/86 DURING
PROCEDURE AND
CARDIOLOGIST FELT THE
NEED T OBSERVE SUBJECT
OVERNIGHT.

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

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

AEID	
Adverse event	CORONARY ARTERY DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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AEID	USA-US067-2020-MRNA-1273-P30 1000013
Adverse event	WORSENING AORTIC ANEURYSM
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	27 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	06 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT STATES SHE WAS ADMITTED TO PIEDMONT ATLANTA ON 10/27/2020, HAD CABG DONE ON 10/28/2020 AND WAS RELEASED ON 11/06/2020.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

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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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	09 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEART HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 JAN 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication METOPROLOL SUCCINATE
EXTENDED RELEASE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		1 JAN 2016
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

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 (4)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 FEB 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHES, OCCASIONAL

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 (5)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication EZETIMIBE

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

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 (6)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	1 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	08 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (7)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	9 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	06 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication PRAZOSIN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (8)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		9 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN, LEFT
ARM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PAIN, PROCEDURE CORONARY
ARTERY BYPASS GRAFT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	06 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication AUGMENTIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR POST
SURGERY INFECTION

Dose per administration 875/125

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	06 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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 (12)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication BACITRACIN 500G

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS, WOUND
INFECTION POST PROCEDURE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	06 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS, ANTIPLATELET,
POST CABG PROCEDURE

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS, ANEMIA, POST
CABG PROCEDURE

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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 (16)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication PAIN, POST CORONARY
ARTERY BYPASS GRAFT
PROCEDURE

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	06 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	06 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 975

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 (19)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication ALBUMIN HUMAN

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF AORTIC ANEURYSM

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication AMINOCAPROIC ACID

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication ANTICOAGULANT CITRATE
DEXTROSE SOLUTION A

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC
ANEURYSM

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	06 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication ABSORBIC ACID

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication ASPIRIN (CHEWABLE)

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication ASPIRIN (EC)

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication BACITRACIN INJECTION
(IRRIGATION CHEST)

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC
ANEURYSM

Dose per administration 100,000

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INJECTION	
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	28 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication BACITRACIN OINTMENT

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration UNK

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

If dose unit is Other, specify UNITS/GRAM

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication BUMETANIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		01 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication BUMETANIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 (30)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		31 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication BUPIVACAINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input checked="" type="checkbox"/>
If route of administration is Other, specify	LOCAL INFILTRATION CHEST	
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication CALCIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 (32)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication CARDIOPLEGIC SOLUTION

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration SLIDING SCALE

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 (34)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication CHLORHEXIDINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication CHLOREXIDINE GLUCONATE
2%

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC
ANEURYSM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	30 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		30 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication DEXMEDETOMIDINE IN
DEXTROSE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC
ANEURYSM

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify MCG/KG/HR

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

If frequency is Other, specify

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) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication DEXTROSE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication DEXTROSE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify ML/HR

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	06 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication ELECTROLYTE-R (PH7.4)

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication EPINEPHRINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify ML/HR

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication ESOMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 (44)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication EZETIMIBE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 (48)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify UNITS/ML

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication HYDROCORTISONE SOD
SUCCINATE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC
ANEURYSM

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication INSULIN DETEMIR

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	30 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication INSULIN LISPRO

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	30 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	03 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication INSULIN REGULAR

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify ML/HR

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

If frequency is Other, specify

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) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify ML/HR

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication LIDOCAINE PATCH 4%

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication MAGNESIUM SULFATE IN
SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC
ANEURYSM

Dose per administration 100

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

If dose unit is Other, specify ML/HR

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication MAGNESIUM SULFATE IN WATER

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 2/50

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

If dose unit is Other, specify G/ML/HR

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication MAGNESIUM SULFATE IN WATER

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 4/50

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

If dose unit is Other, specify G/ML/HR

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication MANNITOL

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication METOPROLOL TARTATE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication MEDODRINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		31 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication MILRINONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify ML/HR

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication MUPIROCIN 2%

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication NOREPINEPHRINE BITARTRATE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify ML/HR

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 (72)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 (73)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication PIPERACILLIN-TAZOBACTAM

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 24

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

If dose unit is Other, specify ML/HR

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	06 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication POLYETHYLENE GLYCOL

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 17

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 20

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

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	02 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 40

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

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 60

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

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 20

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

If dose unit is Other, specify MEQ

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication	PROPOFOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	WORSENING AORTIC ANEURYSM
Dose per administration	SLIDING SCALE
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	ML/HR
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication SODIUM BICARBONATE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication SODIUM BICARBONATE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Data signed: (b) (4) 20 Apr 2021 21:22:19

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	EPIDURAL	
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	28 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	IRRIGATION	
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	28 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication SODIUM PHOSPHATE 20 MMOL
IN DEXTROSE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC
ANEURYSM

Dose per administration 62.5

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

If dose unit is Other, specify ML/HR

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	IMPLANT/CHEST	
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	28 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication VASOPRESSIN IN SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify ML/HR

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication WORSENING AORTIC ANEURYSM

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 10 Feb 2021 20:11:45

Generated On: 09 Jun 2021 16:11:06

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 10 Feb 2021 20:11:45

Generated On: 09 Jun 2021 16:11:06

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
09 OCT 2020	CARDIAC CATHETERIZATION	Adverse Event	
28 OCT 2020	I-V CORONARY ARTERY BYPASS GRAFT	Adverse Event	
28 OCT 2020	ASCENDING AORTIC REPLACEMENT	Adverse Event	

US3242231

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:11:06

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3242231

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:11:06

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

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*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

SAEID	USA-US067-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

SAEID	USA-US067-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	12/SEP/2020 15:08
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

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

SAEID	USA-US067-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	22/SEP/2020 11:35
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

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

SAEID	USA-US067-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

SAEID	USA-US067-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	18/NOV/2020 09:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

SAEID	USA-US067-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	02/DEC/2020 14:36
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

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

SAEID	USA-US067-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	10/DEC/2020 11:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 20 Apr 2021 21:22:19

Generated On: 09 Jun 2021 16:11:06

SAEID	USA-US067-2020-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	NATHAN
Investigator's Last Name	SEGALL
Site Address: Street	175 COUNTRY CLUB DR ST100A
Site Address: City	STOCKBRIDGE
Site Address: State	GA
Site Address: Postal Code	30281
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/MAR/2021 10:36
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

US3242231 (Prod: Clinical Research Atlanta - ERN-PPDS)

US3242231

Form: Participant Creation

Generated On: 09 Jun 2021 16:11:06

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:32
User entered 'US3242231'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 14:05:10

US3242231

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:42
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 14:06:35

US3242231

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:42
User entered '27 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 14:05:11

US3242231

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:42
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	27 Aug 2020 14:06:35

US3242231

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'SCRN'	(b) (4), (b) (6) System	27 Aug 2020 14:06:35

US3242231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:06

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:51
User entered (b) (6) 1943'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 14:05:12

US3242231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:06

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:51
User entered '76'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:04

US3242231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:06

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'YEARS'	(b) (4), (b) (6) System	27 Aug 2020 14:29:04

US3242231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:06

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User entered '76'	System	27 Aug 2020 14:29:31
User entered empty.	System	27 Aug 2020 14:29:17

US3242231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:06

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:51
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit2 Day29: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:22:09
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit2 Day29: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	19 Oct 2020 12:49:32
User entered 'Female (F)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Oct 2020 12:49:22
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity for Visit1 Day1 and Visit2 Day29: Sex (Male) recorded on this form does not match with the Sex (Female) reported in PPD Central lab. Please reconcile the correct Sex and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 07:51:59
User entered 'Male (M)'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:04

US3242231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:06

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:51
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:04

US3242231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:06

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:51
User entered 'I'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:04

US3242231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:06

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:51
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:04

US3242231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:06

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:51
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:04

US3242231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:06

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:51
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:04

US3242231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:06

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:51
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:04

US3242231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:51
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:04

US3242231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:06

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:51
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 14:29:04

US3242231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:06

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:51
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:04

US3242231

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:11:06

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:49:51
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:04

US3242231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:06

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:07
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 14:29:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 14:29:31
User entered '27 Aug 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	27 Aug 2020 14:29:31
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 14:29:17
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 14:29:17

US3242231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User entered 'Aug 2020'	System	27 Aug 2020 14:29:31
User entered empty.	System	27 Aug 2020 14:29:17

US3242231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User entered '2020'	System	27 Aug 2020 14:29:31
User entered empty.	System	27 Aug 2020 14:29:17

US3242231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:06

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:07
User entered 'Amendment 3 (3)'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:17

US3242231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:07
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:17

US3242231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:06

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:07
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 14:29:17

US3242231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:06

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:07
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 14:29:17

US3242231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:06

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:07
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:17

US3242231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:06

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:07
User entered empty.	RWS_ENDPOINT	27 Aug 2020 14:05:11
	ENDPOINT (b) (4)	
	(b) (4)	

US3242231

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:11:06

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'I'	(b) (4), (b) (6) System	27 Aug 2020 14:29:37

US3242231

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:37

US3242231

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:11:06

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:47
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 14:29:46

US3242231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:19:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:19:05
	(b) (4)	
Data point term sent to Coder	System	27 Aug 2020 14:30:47
User entered 'Hypertension'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:02

US3242231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'Un UNK 1995'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:02

US3242231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:02

US3242231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:02

US3242231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 14:30:02

US3242231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:02

US3242231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'Jan 1995'	(b) (4), (b) (6) System	27 Aug 2020 14:30:02

US3242231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered '1995'	(b) (4), (b) (6) System	27 Aug 2020 14:30:02

US3242231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	27 Aug 2020 14:30:02

US3242231

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	27 Aug 2020 14:30:02

US3242231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:19:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:19:04
	(b) (4)	
Data point term sent to Coder	System	27 Aug 2020 14:30:49
User entered 'Gastroesophageal reflux disease'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:14

US3242231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'Un UNK 2018'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:14

US3242231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:06

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:14

US3242231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:14

US3242231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 14:30:14

US3242231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:14

US3242231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'Jan 2018'	(b) (4), (b) (6) System	27 Aug 2020 14:30:14

US3242231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered '2018'	(b) (4), (b) (6) System	27 Aug 2020 14:30:14

US3242231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	27 Aug 2020 14:30:14

US3242231

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	27 Aug 2020 14:30:14

US3242231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:06

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:19:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:19:06
	(b) (4)	
Data point term sent to Coder	System	27 Aug 2020 14:30:49
User entered 'Postmenopausal'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:25

US3242231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'UN UNK 1976'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:25

US3242231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:25

US3242231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:25

US3242231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 14:30:25

US3242231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:25

US3242231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'Jan 1976'	(b) (4), (b) (6) System	27 Aug 2020 14:30:25

US3242231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered '1976'	(b) (4), (b) (6) System	27 Aug 2020 14:30:25

US3242231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	27 Aug 2020 14:30:25

US3242231

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	27 Aug 2020 14:30:25

US3242231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:19:14
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:19:14
	(b) (4)	
Data point term sent to Coder	System	27 Aug 2020 14:31:50
User entered 'Endometriosis'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:58

US3242231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'Un UNK 1970'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:58

US3242231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:06

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:58

US3242231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:58

US3242231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'UN UNK 1975'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:58

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:30:58

US3242231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'Jan 1970'	(b) (4), (b) (6) System	27 Aug 2020 14:30:58

US3242231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered '1970'	(b) (4), (b) (6) System	27 Aug 2020 14:30:58

US3242231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'Jan 1975'	(b) (4), (b) (6) System	27 Aug 2020 14:30:58

US3242231

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered '1975'	(b) (4), (b) (6) System	27 Aug 2020 14:30:58

US3242231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User coded data point as SOC: Hepatobiliary disorders, HLG: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Hepatic steatosis, LLT: Fatty liver - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:19:14
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:19:14
	(b) (4)	
Data point term sent to Coder	System	27 Aug 2020 14:31:51
User entered 'Fatty Liver'	Donna Toepfer (b) (4)	27 Aug 2020 14:31:10

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'Un UNK 2015'	Donna Toepfer (b) (4)	27 Aug 2020 14:31:10

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:06

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:31:10

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 14:31:10

US3242231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 14:31:10

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:31:10

US3242231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'Jan 2015'	(b) (4), (b) (6) System	27 Aug 2020 14:31:10

US3242231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered '2015'	(b) (4), (b) (6) System	27 Aug 2020 14:31:10

US3242231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	27 Aug 2020 14:31:10

US3242231

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	27 Aug 2020 14:31:10

US3242231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User closed query "'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 23:17:51
User closed query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 23:17:15
Query "'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	22 Oct 2020 19:25:49
User opened query "'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:34:37
Query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	16 Sep 2020 13:41:08
User opened query 'Per DM CLR: Please review the status of this procedure as the effects of the procedure may be Ongoing but the procedure itself is not. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 09:18:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:19:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:19:13

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:06

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	27 Aug 2020 14:31:51
User entered 'Hysterectomy'	Donna Toepfer (b) (4)	27 Aug 2020 14:31:22

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'UN UNK 1975'	Donna Toepfer (b) (4)	27 Aug 2020 14:31:22

US3242231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:31:22

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Sep 2020 13:41:03
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 14:31:22

US3242231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'Un UNK 1975' reason for change: Data Entry Error	Donna Toepfer (b) (4)	16 Sep 2020 13:41:03
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 14:31:22

US3242231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:31:22

US3242231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'Jan 1975'	(b) (4), (b) (6) System	27 Aug 2020 14:31:22

US3242231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered '1975'	(b) (4), (b) (6) System	27 Aug 2020 14:31:22

US3242231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'Jan 1975'	(b) (4), (b) (6)	
	System	16 Sep 2020 13:41:03
User entered empty.	System	27 Aug 2020 14:31:22

US3242231

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered '1975'	(b) (4), (b) (6)	
	System	16 Sep 2020 13:41:03
User entered empty.	System	27 Aug 2020 14:31:22

US3242231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 14:12:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 14:12:50
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 10:44:36
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 10:44:36
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:19:13
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:19:13
Data point term sent to Coder	System	27 Aug 2020 14:31:51
User entered 'Drug allergy-Ibuprofen'	Donna Toepfer (b) (4)	27 Aug 2020 14:31:45

US3242231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '1 Jan 1990'	Donna Toepfer (b) (4)	27 Aug 2020 14:31:45

US3242231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:31:45

US3242231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 14:31:45

US3242231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 14:31:45

US3242231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:31:45

US3242231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'Jan 1990'	(b) (4), (b) (6) System	27 Aug 2020 14:31:45

US3242231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered '1990'	(b) (4), (b) (6) System	27 Aug 2020 14:31:45

US3242231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	27 Aug 2020 14:31:45

US3242231

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	27 Aug 2020 14:31:45

US3242231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 15:25:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 15:25:38
	(b) (4)	
Data point term sent to Coder	System	28 Aug 2020 15:25:03
User entered 'Headaches, Occasional'	Donna Toepfer (b) (4)	28 Aug 2020 15:25:00

US3242231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'UN UNK 2018'	Donna Toepfer (b) (4)	28 Aug 2020 15:25:00

US3242231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	28 Aug 2020 15:25:00

US3242231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	28 Aug 2020 15:25:00

US3242231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered empty.	Donna Toepfer (b) (4)	28 Aug 2020 15:25:00

US3242231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	28 Aug 2020 15:25:00

US3242231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:06

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'Jan 2018'	(b) (4), (b) (6) System	28 Aug 2020 15:25:00

US3242231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered '2018'	(b) (4), (b) (6) System	28 Aug 2020 15:25:00

US3242231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	28 Aug 2020 15:25:00

US3242231

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	28 Aug 2020 15:25:00

US3242231

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 15:48:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 15:48:06
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 15:46:54
Coding entries removed.	Donna Toepfer (b) (4)	15 Dec 2020 15:46:43
User entered 'Hyperlipidemia' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 15:46:43
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4)	15 Dec 2020 15:46:24
Data point term sent to Coder	System	16 Sep 2020 13:50:18
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4)	16 Sep 2020 13:49:22
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 13:46:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 13:46:36
	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 13:45:09
User entered 'Hypercholesterolemia'	Donna Toepfer (b) (4)	16 Sep 2020 13:44:30

US3242231

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).		15 Dec 2020 15:46:43
User entered '24 Oct 2016' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 15:46:43
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	15 Dec 2020 15:46:24
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4)	15 Dec 2020 15:46:24
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).		16 Sep 2020 13:49:22
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4)	16 Sep 2020 13:49:22
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	16 Sep 2020 13:44:30
User entered '1 Sep 2020'	Donna Toepfer (b) (4)	16 Sep 2020 13:44:30

US3242231

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4)	15 Dec 2020 15:46:24
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4)	16 Sep 2020 13:49:22
User entered '0'	Donna Toepfer (b) (4)	16 Sep 2020 13:44:30

US3242231

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4)	15 Dec 2020 15:46:24
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4)	16 Sep 2020 13:49:22
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	16 Sep 2020 13:44:30

US3242231

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4)	15 Dec 2020 15:46:24
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4)	16 Sep 2020 13:49:22
User entered empty.	Donna Toepfer (b) (4)	16 Sep 2020 13:44:30

US3242231

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4)	15 Dec 2020 15:46:24
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4)	16 Sep 2020 13:49:22
User entered '0'	Donna Toepfer (b) (4)	16 Sep 2020 13:44:30

US3242231

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User entered 'Oct 2016'	System	15 Dec 2020 15:46:43
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4)	15 Dec 2020 15:46:24
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4)	16 Sep 2020 13:49:22
User entered 'Sep 2020'	System	16 Sep 2020 13:44:30

US3242231

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User entered '2016'	System	15 Dec 2020 15:46:43
DataPoint activated with code reason code Data required.	Donna Toepfer (b) (4)	15 Dec 2020 15:46:24
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4)	16 Sep 2020 13:49:22
User entered '2020'	System	16 Sep 2020 13:44:30

US3242231

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6) Donna Toepfer (b) (4)	15 Dec 2020 15:46:24
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4)	16 Sep 2020 13:49:22
User entered empty.	System	16 Sep 2020 13:44:30

US3242231

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
DataPoint activated with code reason code Data required.	(b) (4), (b) (6) Donna Toepfer (b) (4)	15 Dec 2020 15:46:24
DataPoint inactivated with code reason code Data not required.	Donna Toepfer (b) (4)	16 Sep 2020 13:49:22
User entered empty.	System	16 Sep 2020 13:44:30

US3242231

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User coded data point as SOC: Renal and urinary disorders, HLG: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 13:46:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 13:46:35
	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 13:45:10
User entered 'Chronic Kidney Disease Stage 3'	Donna Toepfer (b) (4)	16 Sep 2020 13:44:56

US3242231

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'Un UNK 2015'	Donna Toepfer (b) (4)	16 Sep 2020 13:44:56

US3242231

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	16 Sep 2020 13:44:56

US3242231

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	16 Sep 2020 13:44:56

US3242231

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered empty.	Donna Toepfer (b) (4)	16 Sep 2020 13:44:56

US3242231

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	16 Sep 2020 13:44:56

US3242231

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'Jan 2015'	(b) (4), (b) (6) System	16 Sep 2020 13:44:56

US3242231

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered '2015'	(b) (4), (b) (6) System	16 Sep 2020 13:44:56

US3242231

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	16 Sep 2020 13:44:56

US3242231

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	16 Sep 2020 13:44:56

US3242231

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User coded data point as SOC: Vascular disorders, HLGT: Aneurysms and artery dissections, HLT: Aortic aneurysms and dissections, PT: Aortic aneurysm, LLT: Thoracic aortic aneurysm - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 07:25:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 07:25:43
	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 13:46:10
User entered 'Thoracic Aortic Aneurysm without rupture'	Donna Toepfer (b) (4)	16 Sep 2020 13:45:20

US3242231

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'UN UNK 2017'	Donna Toepfer (b) (4)	16 Sep 2020 13:45:20

US3242231

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	16 Sep 2020 13:45:20

US3242231

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	16 Sep 2020 13:45:20

US3242231

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered empty.	Donna Toepfer (b) (4)	16 Sep 2020 13:45:20

US3242231

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:33
User entered '0'	Donna Toepfer (b) (4)	16 Sep 2020 13:45:20

US3242231

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'Jan 2017'	(b) (4), (b) (6) System	16 Sep 2020 13:45:20

US3242231

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered '2017'	(b) (4), (b) (6) System	16 Sep 2020 13:45:20

US3242231

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	16 Sep 2020 13:45:20

US3242231

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	16 Sep 2020 13:45:20

US3242231

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:11:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
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.	Coder Import (b) (4)	15 Dec 2020 15:48:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 15:48:59
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 15:47:55
User entered 'Obesity'	Donna Toepfer (b) (4)	15 Dec 2020 15:47:01

US3242231

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '24 Oct 2016'	Donna Toepfer (b) (4)	15 Dec 2020 15:47:01

US3242231

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '0'	Donna Toepfer (b) (4)	15 Dec 2020 15:47:01

US3242231

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:11:06

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	15 Dec 2020 15:47:01

US3242231

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered empty.	Donna Toepfer (b) (4)	15 Dec 2020 15:47:01

US3242231

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:11:06

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '0'	Donna Toepfer (b) (4)	15 Dec 2020 15:47:01

US3242231

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'Oct 2016'	(b) (4), (b) (6) System	15 Dec 2020 15:47:01

US3242231

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered '2016'	(b) (4), (b) (6) System	15 Dec 2020 15:47:01

US3242231

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	15 Dec 2020 15:47:01

US3242231

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	15 Dec 2020 15:47:01

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:27
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 14:32:36

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:27
User entered '27 Aug 2020'	Donna Toepfer (b) (4)	27 Aug 2020 14:32:36

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:27
User entered '09:44'	Donna Toepfer (b) (4)	27 Aug 2020 14:32:36

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered '27 Aug 2020 09:44'	(b) (4), (b) (6) System	27 Aug 2020 14:32:36

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:27
User entered '62' in	Donna Toepfer (b) (4)	27 Aug 2020 14:32:36
DataPoint set to visible.	System	27 Aug 2020 14:29:37

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:27
User entered '174' lb	Donna Toepfer (b) (4)	27 Aug 2020 14:32:36
DataPoint set to visible.	System	27 Aug 2020 14:29:37

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
Amendment Manager: User entered '31.89156'	(b) (4), (b) (6)	
User entered '31.9'	System	17 Sep 2020 00:05:01
DataPoint set to visible.	System	27 Aug 2020 14:32:36
	System	27 Aug 2020 14:29:37

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'kg/m2'	(b) (4), (b) (6)	27 Aug 2020 14:32:36
DataPoint set to visible.	System	27 Aug 2020 14:29:37

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:27
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	27 Aug 2020 14:32:36

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:27
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 14:32:36

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:27
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 14:32:36

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:27
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	27 Aug 2020 14:32:36

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'bpm'	(b) (4), (b) (6) System	27 Aug 2020 14:32:36

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:27
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	27 Aug 2020 14:32:36

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'breaths/min'	(b) (4), (b) (6) System	27 Aug 2020 14:32:36

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:27
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	27 Aug 2020 14:32:36

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'mmHg'	(b) (4), (b) (6) System	27 Aug 2020 14:32:36

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:27
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	27 Aug 2020 14:32:36

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'mmHg'	(b) (4), (b) (6) System	27 Aug 2020 14:32:36

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 11:57:28

US3242231

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 11:57:28

US3242231

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:54:19
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 14:32:01

US3242231

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:54:19
User entered '27 Aug 2020'	Donna Toepfer (b) (4)	27 Aug 2020 14:32:01

US3242231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:54:35
User entered '27 Aug 2020'	Donna Toepfer (b) (4)	19 Oct 2020 12:50:15

US3242231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:11:06

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:54:35
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Oct 2020 12:50:15

US3242231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:11:06

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:54:35
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 19:26:27
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Donna Toepfer (b) (4)	19 Oct 2020 12:50:15

US3242231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:11:06

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:54:35
User entered empty.	Donna Toepfer (b) (4)	19 Oct 2020 12:50:15

US3242231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:11:06

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:54:35
User entered 'UN UNK 1975' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 19:26:27
User entered empty.	Donna Toepfer (b) (4)	19 Oct 2020 12:50:15

US3242231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:11:06

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:54:35
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 12:50:15

US3242231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:11:06

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:54:35
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 19:26:27
User entered 'UN UNK 1975' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Oct 2020 19:25:33
User entered 'UN UNK 1976'	Donna Toepfer (b) (4)	19 Oct 2020 12:50:15

US3242231

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:11:06

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:54:35
User entered '0'	Donna Toepfer (b) (4)	19 Oct 2020 12:50:15

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered 'retired, shops in community several times a week'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered 'I'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:11:06

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:50:47
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 14:33:19

US3242231

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:54:01
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:30

US3242231

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:54:01
User entered '27 Aug 2020'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:30

US3242231

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:54:01
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:30

US3242231

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'VISIT1'	System	27 Aug 2020 14:33:30

US3242231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:09
User entered '27 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 19:24:18

US3242231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:09
User entered '188735'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Aug 2020 19:24:18

US3242231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:09
User entered '>=65 years (3)'	RWS_ENDPOINT	27 Aug 2020 19:24:18
	ENDPOINT (b) (4)	
	(b) (4)	

US3242231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:06

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:09
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:41

US3242231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:06

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:09
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:41

US3242231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:09
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:41

US3242231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:06

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:09
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:41

US3242231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:06

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:09
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:41

US3242231

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:09
User entered 'No (N)'	Erynn McKinley (b) (4)	23 Sep 2020 18:45:21
	(b) (4)	
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:12:31
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:12:29

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered '27 Aug 2020'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered '10:09'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered '27 Aug 2020 10:09'	(b) (4), (b) (6)	11 Sep 2020 18:52:06
	System	

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered '98.1' F	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered '68'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'bpm'	(b) (4), (b) (6) System	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered '16'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered '138'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered '80'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:06

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:11:06

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered missing code ND - Not Done.	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered '27 Aug 2020'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered '16:23'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered '27 Aug 2020 16:23'	(b) (4), (b) (6)	11 Sep 2020 18:52:06
	System	

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered '97.9' F	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered '64'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'bpm'	System	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered '16'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'breaths/min'	(b) (4), (b) (6) System	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered '130'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:20
User entered '80'	Donna Toepfer (b) (4)	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'mmHg'	(b) (4), (b) (6) System	11 Sep 2020 18:52:06

US3242231

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:54:51
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 19:30:34

US3242231

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:54:51
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:30:34

US3242231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:29
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 19:56:57

US3242231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:29
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:56:57

US3242231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:29
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:56:57

US3242231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6)	27 Aug 2020 19:56:57
	System	

US3242231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:29
User entered '27 Aug 2020'	Donna Toepfer (b) (4)	27 Aug 2020 19:56:57

US3242231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:29
User entered '15:53'	Donna Toepfer (b) (4)	27 Aug 2020 19:56:57

US3242231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
User entered '27 Aug 2020 15:53'	(b) (4), (b) (6)	27 Aug 2020 19:56:57
	System	

US3242231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:51:29
User entered 'Left Arm (LEFT ARM)'	Donna Toepfer (b) (4)	27 Aug 2020 19:56:57

US3242231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 19:51:29
User entered 'ONCE'	System	27 Aug 2020 19:56:57

US3242231

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6)	27 Aug 2020 19:56:57
	System	

US3242231

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:55:12
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 19:30:55

US3242231

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:55:12
User entered '27 Aug 2020'	Donna Toepfer (b) (4)	27 Aug 2020 19:30:55

US3242231

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:55:12
User entered '10:44'	Donna Toepfer (b) (4)	27 Aug 2020 19:30:55

US3242231

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
User entered '27 Aug 2020 10:44'	(b) (4), (b) (6)	27 Aug 2020 19:30:55
	System	

US3242231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:11:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:55:29
User entered '27 Aug 2020'	Donna Toepfer (b) (4)	27 Aug 2020 19:31:11

US3242231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Donna Toepfer (b) (4)	27 Aug 2020 19:31:11

US3242231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:55:29
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 19:31:11

US3242231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:55:29
User entered '10:39'	Donna Toepfer (b) (4)	27 Aug 2020 19:31:11

US3242231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
User entered '27 Aug 2020 10:39'	(b) (4), (b) (6)	27 Aug 2020 19:31:11
	System	

US3242231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Donna Toepfer (b) (4)	27 Aug 2020 19:31:11

US3242231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:55:29
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 19:31:11

US3242231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:55:29
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:31:11

US3242231

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 19:31:11
	System	

US3242231

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:55:55
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 19:31:17

US3242231

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
User entered 'I'	(b) (4), (b) (6)	27 Aug 2020 19:31:17
	System	

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:32:21', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8afb7fe5-4251-43c4-9fe4-a7d71b655496'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	27 Aug 2020 20:33:24

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:32:45', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8afb7fe5-4251-43c4-9fe4-a7d71b655496' User entered '97.9'	(b) (4), (b) (6) System	27 Aug 2020 20:33:24
	System	27 Aug 2020 20:33:24

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:33:03', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8afb7fe5-4251-43c4-9fe4-a7d71b655496'	(b) (4), (b) (6)	
User entered 'No (N)'	System	27 Aug 2020 20:33:24

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:33:20', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8afb7fe5-4251-43c4-9fe4-a7d71b655496' User entered '27 Aug 2020 16:33'	(b) (4), (b) (6) System	27 Aug 2020 20:33:24
	System	27 Aug 2020 20:33:24

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '27 Aug 2020 16:13'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '27 Aug 2020 18:43'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:51:02', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '4845eff5-7586-4abe-b6c5-3c355dda348a' User entered 'Yes (Y)'	(b) (4), (b) (6) System	28 Aug 2020 00:51:38
	System	28 Aug 2020 00:51:38

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:51:14', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '4845eff5-7586-4abe-b6c5-3c355dda348a' User entered '96.8'	(b) (4), (b) (6) System	28 Aug 2020 00:51:38
	System	28 Aug 2020 00:51:38

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:51:25', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '4845eff5-7586-4abe-b6c5-3c355dda348a' User entered 'No (N)'	(b) (4), (b) (6) System	28 Aug 2020 00:51:38
	System	28 Aug 2020 00:51:38

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:51:33', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '4845eff5-7586-4abe-b6c5-3c355dda348a' User entered '27 Aug 2020 20:51'	(b) (4), (b) (6) System	28 Aug 2020 00:51:38
	System	28 Aug 2020 00:51:38

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '27 Aug 2020 19:38'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 2'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:48:36', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '5289634e-aab7-4ba0-a004-6411f82e7ae8' User entered 'Yes (Y)'	(b) (4), (b) (6) System	29 Aug 2020 00:49:12
	System	29 Aug 2020 00:49:12

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:48:47', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '5289634e-aab7-4ba0-a004-6411f82e7ae8' User entered '97.2'	(b) (4), (b) (6) System	29 Aug 2020 00:49:12
	System	29 Aug 2020 00:49:12

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:48:56', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '5289634e-aab7-4ba0-a004-6411f82e7ae8' User entered 'No (N)'	(b) (4), (b) (6) System	29 Aug 2020 00:49:12
	System	29 Aug 2020 00:49:12

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:49:09', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '5289634e-aab7-4ba0-a004-6411f82e7ae8' User entered '28 Aug 2020 20:49'	(b) (4), (b) (6) System	29 Aug 2020 00:49:12
	System	29 Aug 2020 00:49:12

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '28 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '29 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 3'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:50:10', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '24f40de0-fb49-4b72-8fbe-f429580a9164'	(b) (4), (b) (6)	
	System	30 Aug 2020 11:50:35
User entered 'Yes (Y)'	System	30 Aug 2020 11:50:35

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:50:19', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '24f40de0-fb49-4b72-8fbe-f429580a9164' User entered '97.6'	(b) (4), (b) (6) System	30 Aug 2020 11:50:35
	System	30 Aug 2020 11:50:35

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:50:25', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '24f40de0-fb49-4b72-8fbe-f429580a9164'	(b) (4), (b) (6)	
User entered 'No (N)'	System	30 Aug 2020 11:50:35

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:50:31', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '24f40de0-fb49-4b72-8fbe-f429580a9164' User entered '30 Aug 2020 07:50'	(b) (4), (b) (6) System	30 Aug 2020 11:50:35
	System	30 Aug 2020 11:50:35

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '29 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '30 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 4'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:41:26', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'a8272191-65ad-430a-97fb-f95399e04770' User entered 'Yes (Y)'	(b) (4), (b) (6) System	31 Aug 2020 12:42:04
	System	31 Aug 2020 12:42:04

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:41:50', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'a8272191-65ad-430a-97fb-f95399e04770' User entered '97.5'	(b) (4), (b) (6) System	31 Aug 2020 12:42:04
	System	31 Aug 2020 12:42:04

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:41:56', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'a8272191-65ad-430a-97fb-f95399e04770'	(b) (4), (b) (6)	
User entered 'No (N)'	System	31 Aug 2020 12:42:04

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:42:03', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'a8272191-65ad-430a-97fb-f95399e04770' User entered '31 Aug 2020 08:42'	(b) (4), (b) (6) System	31 Aug 2020 12:42:04
	System	31 Aug 2020 12:42:04

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '30 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '31 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 5'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:26:52', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8ee81440-7742-43d9-a660-d3d357d671e7' User entered 'Yes (Y)'	(b) (4), (b) (6) System	01 Sep 2020 01:28:09
	System	01 Sep 2020 01:28:09

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:27:46', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8ee81440-7742-43d9-a660-d3d357d671e7' User entered '96.8'	(b) (4), (b) (6) System	01 Sep 2020 01:28:09
	System	01 Sep 2020 01:28:09

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:27:52', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8ee81440-7742-43d9-a660-d3d357d671e7'	(b) (4), (b) (6)	
User entered 'No (N)'	System	01 Sep 2020 01:28:09

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:28:06', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8ee81440-7742-43d9-a660-d3d357d671e7' User entered '31 Aug 2020 21:28'	(b) (4), (b) (6) System	01 Sep 2020 01:28:09
	System	01 Sep 2020 01:28:09

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '31 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '01 Sep 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 6'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:04:52', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'c06672c9-559a-4263-8d54-0a77521fdcf9' User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Sep 2020 02:05:27
	System	02 Sep 2020 02:05:27

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:05:06', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'c06672c9-559a-4263-8d54-0a77521fdcf9' User entered '96.5'	(b) (4), (b) (6) System	02 Sep 2020 02:05:27
	System	02 Sep 2020 02:05:27

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:05:14', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'c06672c9-559a-4263-8d54-0a77521fdcf9' User entered 'No (N)'	(b) (4), (b) (6) System	02 Sep 2020 02:05:27
	System	02 Sep 2020 02:05:27

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:05:23', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'c06672c9-559a-4263-8d54-0a77521fdcf9' User entered '01 Sep 2020 22:05'	(b) (4), (b) (6) System	02 Sep 2020 02:05:27
	System	02 Sep 2020 02:05:27

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '01 Sep 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '02 Sep 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 7'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:27:55', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'db161803-4776-4090-b91c-7738dd5e2a37'	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	02 Sep 2020 23:28:35

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:28:19', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'db161803-4776-4090-b91c-7738dd5e2a37' User entered '98.0'	(b) (4), (b) (6) System	02 Sep 2020 23:28:35
	System	02 Sep 2020 23:28:35

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:28:27', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'db161803-4776-4090-b91c-7738dd5e2a37'	(b) (4), (b) (6)	
User entered 'No (N)'	System	02 Sep 2020 23:28:35

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:28:32', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'db161803-4776-4090-b91c-7738dd5e2a37'	(b) (4), (b) (6)	
User entered '02 Sep 2020 19:28'	System	02 Sep 2020 23:28:35

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '02 Sep 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '03 Sep 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:33:33', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'f7b8dc73-afc2-485c-b858-8a410cebee56'	(b) (4), (b) (6)	27 Aug 2020 20:34:15
User entered 'None (1)'	System	27 Aug 2020 20:34:15

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:33:50', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'f7b8dc73-afc2-485c-b858-8a410cebee56'	(b) (4), (b) (6)	
User entered 'No (N)'	System	27 Aug 2020 20:34:15

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:33:56', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'f7b8dc73-afc2-485c-b858-8a410cebee56'	(b) (4), (b) (6)	
User entered 'No (N)'	System	27 Aug 2020 20:34:15

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:34:02', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'f7b8dc73-afc2-485c-b858-8a410cebee56'	(b) (4), (b) (6)	27 Aug 2020 20:34:15
User entered 'None (1)'	System	27 Aug 2020 20:34:15

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:34:10', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'f7b8dc73-afc2-485c-b858-8a410cebee56' User entered '27 Aug 2020 16:34'	(b) (4), (b) (6) System	27 Aug 2020 20:34:15
	System	27 Aug 2020 20:34:15

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '27 Aug 2020 16:13'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '27 Aug 2020 18:43'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:51:45', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd86b68dc-a90e-4344-936b-3dfb65e012ca' User entered 'None (1)'	(b) (4), (b) (6) System	28 Aug 2020 00:52:59
	System	28 Aug 2020 00:52:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:52:29', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd86b68dc-a90e-4344-936b-3dfb65e012ca' User entered 'No (N)'	(b) (4), (b) (6) System	28 Aug 2020 00:52:59
	System	28 Aug 2020 00:52:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:52:41', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd86b68dc-a90e-4344-936b-3dfb65e012ca' User entered 'No (N)'	(b) (4), (b) (6) System	28 Aug 2020 00:52:59
	System	28 Aug 2020 00:52:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:52:47', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd86b68dc-a90e-4344-936b-3dfb65e012ca' User entered 'None (1)'	(b) (4), (b) (6) System	28 Aug 2020 00:52:59
	System	28 Aug 2020 00:52:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:52:57', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd86b68dc-a90e-4344-936b-3dfb65e012ca' User entered '27 Aug 2020 20:52'	(b) (4), (b) (6) System	28 Aug 2020 00:52:59
	System	28 Aug 2020 00:52:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '27 Aug 2020 19:38'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 2'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:49:55', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '35e3c179-42aa-447b-829d-e1737f275ceb'	(b) (4), (b) (6)	
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 00:50:45

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:50:01', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '35e3c179-42aa-447b-829d-e1737f275ceb' User entered 'No (N)'	(b) (4), (b) (6) System	29 Aug 2020 00:50:45
	System	29 Aug 2020 00:50:45

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:50:09', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '35e3c179-42aa-447b-829d-e1737f275ceb' User entered 'No (N)'	(b) (4), (b) (6) System	29 Aug 2020 00:50:45
	System	29 Aug 2020 00:50:45

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:50:24', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '35e3c179-42aa-447b-829d-e1737f275ceb' User entered 'None (1)'	(b) (4), (b) (6) System	29 Aug 2020 00:50:45
	System	29 Aug 2020 00:50:45

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:50:42', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '35e3c179-42aa-447b-829d-e1737f275ceb' User entered '28 Aug 2020 20:50'	(b) (4), (b) (6) System	29 Aug 2020 00:50:45
	System	29 Aug 2020 00:50:45

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '28 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '29 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 3'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:50:37', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '6433f183-d671-4e3c-bf82-6d22d9b0c834' User entered 'None (1)'	(b) (4), (b) (6) System	30 Aug 2020 11:51:01
	System	30 Aug 2020 11:51:01

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:50:43', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '6433f183-d671-4e3c-bf82-6d22d9b0c834' User entered 'No (N)'	(b) (4), (b) (6) System	30 Aug 2020 11:51:01
	System	30 Aug 2020 11:51:01

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:50:46', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '6433f183-d671-4e3c-bf82-6d22d9b0c834' User entered 'No (N)'	(b) (4), (b) (6) System	30 Aug 2020 11:51:01
	System	30 Aug 2020 11:51:01

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:50:52', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '6433f183-d671-4e3c-bf82-6d22d9b0c834' User entered 'None (1)'	(b) (4), (b) (6) System	30 Aug 2020 11:51:01
	System	30 Aug 2020 11:51:01

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:50:59', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '6433f183-d671-4e3c-bf82-6d22d9b0c834' User entered '30 Aug 2020 07:50'	(b) (4), (b) (6) System	30 Aug 2020 11:51:01
	System	30 Aug 2020 11:51:01

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '29 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '30 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 4'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:42:11', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '7589d9f9-5a6d-416f-8ba0-8f7aead75264'	(b) (4), (b) (6)	
User entered 'None (1)'	System	31 Aug 2020 12:42:42

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:42:16', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '7589d9f9-5a6d-416f-8ba0-8f7aecd75264' User entered 'No (N)'	(b) (4), (b) (6) System	31 Aug 2020 12:42:42
	System	31 Aug 2020 12:42:42

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:42:19', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '7589d9f9-5a6d-416f-8ba0-8f7aecd75264' User entered 'No (N)'	(b) (4), (b) (6) System	31 Aug 2020 12:42:42
	System	31 Aug 2020 12:42:42

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:42:27', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '7589d9f9-5a6d-416f-8ba0-8f7aead75264' User entered 'None (1)'	(b) (4), (b) (6) System	31 Aug 2020 12:42:42
	System	31 Aug 2020 12:42:42

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:42:38', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '7589d9f9-5a6d-416f-8ba0-8f7aecd75264' User entered '31 Aug 2020 08:42'	(b) (4), (b) (6) System	31 Aug 2020 12:42:42
	System	31 Aug 2020 12:42:42

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '30 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '31 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 5'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:28:19', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '62a1ad1e-dad6-47f9-84dd-6d719dd24013' User entered 'None (1)'	(b) (4), (b) (6) System	01 Sep 2020 01:28:59
	System	01 Sep 2020 01:28:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:28:30', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '62a1ad1e-dad6-47f9-84dd-6d719dd24013' User entered 'No (N)'	(b) (4), (b) (6) System	01 Sep 2020 01:28:59
	System	01 Sep 2020 01:28:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:28:38', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '62a1ad1e-dad6-47f9-84dd-6d719dd24013' User entered 'No (N)'	(b) (4), (b) (6) System	01 Sep 2020 01:28:59
	System	01 Sep 2020 01:28:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:28:48', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '62a1ad1e-dad6-47f9-84dd-6d719dd24013' User entered 'None (1)'	(b) (4), (b) (6) System	01 Sep 2020 01:28:59
	System	01 Sep 2020 01:28:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:28:56', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '62a1ad1e-dad6-47f9-84dd-6d719dd24013' User entered '31 Aug 2020 21:28'	(b) (4), (b) (6) System	01 Sep 2020 01:28:59
	System	01 Sep 2020 01:28:59

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '31 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '01 Sep 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 6'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:05:31', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '9022cc82-181e-463c-bf9b-95a65c5a623e' User entered 'None (1)'	(b) (4), (b) (6) System	02 Sep 2020 02:06:06
	System	02 Sep 2020 02:06:06

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:05:36', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '9022cc82-181e-463c-bf9b-95a65c5a623e' User entered 'No (N)'	(b) (4), (b) (6) System	02 Sep 2020 02:06:06
	System	02 Sep 2020 02:06:06

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:05:42', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '9022cc82-181e-463c-bf9b-95a65c5a623e' User entered 'No (N)'	(b) (4), (b) (6) System	02 Sep 2020 02:06:06
	System	02 Sep 2020 02:06:06

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:05:48', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '9022cc82-181e-463c-bf9b-95a65c5a623e' User entered 'None (1)'	(b) (4), (b) (6) System	02 Sep 2020 02:06:06
	System	02 Sep 2020 02:06:06

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:05:57', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '9022cc82-181e-463c-bf9b-95a65c5a623e' User entered '01 Sep 2020 22:05'	(b) (4), (b) (6) System	02 Sep 2020 02:06:06
	System	02 Sep 2020 02:06:06

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '01 Sep 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '02 Sep 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 7'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:28:38', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '1288962a-3b44-443c-bab3-d4fe5031e40d' User entered 'None (1)'	(b) (4), (b) (6) System	02 Sep 2020 23:29:15
	System	02 Sep 2020 23:29:15

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:28:55', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '1288962a-3b44-443c-bab3-d4fe5031e40d' User entered 'No (N)'	(b) (4), (b) (6) System	02 Sep 2020 23:29:15
	System	02 Sep 2020 23:29:15

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:29:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '1288962a-3b44-443c-bab3-d4fe5031e40d' User entered 'No (N)'	(b) (4), (b) (6) System	02 Sep 2020 23:29:15
	System	02 Sep 2020 23:29:15

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:29:06', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '1288962a-3b44-443c-bab3-d4fe5031e40d' User entered 'None (1)'	(b) (4), (b) (6) System	02 Sep 2020 23:29:15
	System	02 Sep 2020 23:29:15

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:29:12', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '1288962a-3b44-443c-bab3-d4fe5031e40d' User entered '02 Sep 2020 19:29'	(b) (4), (b) (6) System	02 Sep 2020 23:29:15
	System	02 Sep 2020 23:29:15

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '02 Sep 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '03 Sep 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:34:24', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'a226537b-f862-4e2f-9f57-f0d08ac719c7' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 20:35:08
	System	27 Aug 2020 20:35:08

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:34:27', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'a226537b-f862-4e2f-9f57-f0d08ac719c7' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 20:35:08
	System	27 Aug 2020 20:35:08

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:34:31', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'a226537b-f862-4e2f-9f57-f0d08ac719c7' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 20:35:08
	System	27 Aug 2020 20:35:08

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:34:34', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'a226537b-f862-4e2f-9f57-f0d08ac719c7' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 20:35:08
	System	27 Aug 2020 20:35:08

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:34:39', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'a226537b-f862-4e2f-9f57-f0d08ac719c7' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 20:35:08
	System	27 Aug 2020 20:35:08

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:34:44', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'a226537b-f862-4e2f-9f57-f0d08ac719c7' User entered 'None (0)'	(b) (4), (b) (6) System	27 Aug 2020 20:35:08
	System	27 Aug 2020 20:35:08

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:34:54', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'a226537b-f862-4e2f-9f57-f0d08ac719c7' User entered 'No (N)'	(b) (4), (b) (6) System	27 Aug 2020 20:35:08
	System	27 Aug 2020 20:35:08

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T16:35:02', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'a226537b-f862-4e2f-9f57-f0d08ac719c7' User entered '27 Aug 2020 16:35'	(b) (4), (b) (6) System	27 Aug 2020 20:35:08
	System	27 Aug 2020 20:35:08

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '27 Aug 2020 16:13'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '27 Aug 2020 18:43'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:53:04', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '3daeec49-c6cb-4a28-9993-a8268471b940' User entered 'None (0)'	(b) (4), (b) (6) System	28 Aug 2020 00:53:45
	System	28 Aug 2020 00:53:45

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:53:07', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '3daeec49-c6cb-4a28-9993-a8268471b940' User entered 'None (0)'	(b) (4), (b) (6) System	28 Aug 2020 00:53:45
	System	28 Aug 2020 00:53:45

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:53:13', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '3daeec49-c6cb-4a28-9993-a8268471b940' User entered 'None (0)'	(b) (4), (b) (6) System	28 Aug 2020 00:53:45
	System	28 Aug 2020 00:53:45

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:53:17', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '3daeec49-c6cb-4a28-9993-a8268471b940' User entered 'None (0)'	(b) (4), (b) (6) System	28 Aug 2020 00:53:45
	System	28 Aug 2020 00:53:45

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:53:21', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '3daeec49-c6cb-4a28-9993-a8268471b940' User entered 'None (0)'	(b) (4), (b) (6) System	28 Aug 2020 00:53:45
	System	28 Aug 2020 00:53:45

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:53:25', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '3daeec49-c6cb-4a28-9993-a8268471b940' User entered 'None (0)'	(b) (4), (b) (6) System	28 Aug 2020 00:53:45
	System	28 Aug 2020 00:53:45

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:53:30', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '3daeec49-c6cb-4a28-9993-a8268471b940' User entered 'No (N)'	(b) (4), (b) (6) System	28 Aug 2020 00:53:45
	System	28 Aug 2020 00:53:45

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-27T20:53:43', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '3daeec49-c6cb-4a28-9993-a8268471b940' User entered '27 Aug 2020 20:53'	(b) (4), (b) (6) System	28 Aug 2020 00:53:45
	System	28 Aug 2020 00:53:45

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '27 Aug 2020 19:38'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '28 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 2'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:51:14', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '69de1666-d280-42b6-918f-8c9b0354016a' User entered 'None (0)'	(b) (4), (b) (6) System	29 Aug 2020 00:52:35
	System	29 Aug 2020 00:52:35

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:51:21', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '69de1666-d280-42b6-918f-8c9b0354016a' User entered 'None (0)'	(b) (4), (b) (6) System	29 Aug 2020 00:52:35
	System	29 Aug 2020 00:52:35

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:51:50', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '69de1666-d280-42b6-918f-8c9b0354016a' User entered 'No interference with activity (1)'	(b) (4), (b) (6) System	29 Aug 2020 00:52:35
	System	29 Aug 2020 00:52:35

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:51:56', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '69de1666-d280-42b6-918f-8c9b0354016a' User entered 'None (0)'	(b) (4), (b) (6) System	29 Aug 2020 00:52:35
	System	29 Aug 2020 00:52:35

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:52:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '69de1666-d280-42b6-918f-8c9b0354016a' User entered 'None (0)'	(b) (4), (b) (6) System	29 Aug 2020 00:52:35
	System	29 Aug 2020 00:52:35

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:52:05', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '69de1666-d280-42b6-918f-8c9b0354016a' User entered 'None (0)'	(b) (4), (b) (6) System	29 Aug 2020 00:52:35
	System	29 Aug 2020 00:52:35

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:52:15', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '69de1666-d280-42b6-918f-8c9b0354016a' User entered 'No (N)'	(b) (4), (b) (6) System	29 Aug 2020 00:52:35
	System	29 Aug 2020 00:52:35

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-28T20:52:31', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '69de1666-d280-42b6-918f-8c9b0354016a' User entered '28 Aug 2020 20:52'	(b) (4), (b) (6) System	29 Aug 2020 00:52:35
	System	29 Aug 2020 00:52:35

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '28 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '29 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 3'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:51:05', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd0cbb86c-7e70-4b23-afd7-450daddec291' User entered 'None (0)'	(b) (4), (b) (6) System	30 Aug 2020 11:51:36
	System	30 Aug 2020 11:51:36

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:51:08', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd0cbb86c-7e70-4b23-afd7-450daddec291' User entered 'None (0)'	(b) (4), (b) (6) System	30 Aug 2020 11:51:36
	System	30 Aug 2020 11:51:36

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:51:11', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd0cbb86c-7e70-4b23-afd7-450daddec291' User entered 'None (0)'	(b) (4), (b) (6) System	30 Aug 2020 11:51:36
	System	30 Aug 2020 11:51:36

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:51:16', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd0cbb86c-7e70-4b23-afd7-450daddec291' User entered 'None (0)'	(b) (4), (b) (6) System	30 Aug 2020 11:51:36
	System	30 Aug 2020 11:51:36

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:51:19', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd0cbb86c-7e70-4b23-afd7-450daddec291' User entered 'None (0)'	(b) (4), (b) (6) System	30 Aug 2020 11:51:36
	System	30 Aug 2020 11:51:36

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:51:22', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd0cbb86c-7e70-4b23-afd7-450daddec291' User entered 'None (0)'	(b) (4), (b) (6) System	30 Aug 2020 11:51:36
	System	30 Aug 2020 11:51:36

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:51:27', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd0cbb86c-7e70-4b23-afd7-450daddec291' User entered 'No (N)'	(b) (4), (b) (6) System	30 Aug 2020 11:51:36
	System	30 Aug 2020 11:51:36

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-30T07:51:31', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd0cbb86c-7e70-4b23-afd7-450daddec291' User entered '30 Aug 2020 07:51'	(b) (4), (b) (6) System	30 Aug 2020 11:51:36
	System	30 Aug 2020 11:51:36

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '29 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '30 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 4'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:42:44', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '884328c5-675d-4bb8-8f40-70d6a82fccd6' User entered 'None (0)'	(b) (4), (b) (6) System	31 Aug 2020 12:43:29
	System	31 Aug 2020 12:43:29

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:42:47', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '884328c5-675d-4bb8-8f40-70d6a82fccd6' User entered 'None (0)'	(b) (4), (b) (6) System	31 Aug 2020 12:43:29
	System	31 Aug 2020 12:43:29

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:43:17', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '884328c5-675d-4bb8-8f40-70d6a82fccd6' User entered 'None (0)'	(b) (4), (b) (6) System	31 Aug 2020 12:43:29
	System	31 Aug 2020 12:43:29

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:42:55', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '884328c5-675d-4bb8-8f40-70d6a82fccd6' User entered 'None (0)'	(b) (4), (b) (6) System	31 Aug 2020 12:43:29
	System	31 Aug 2020 12:43:29

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:42:59', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '884328c5-675d-4bb8-8f40-70d6a82fccd6' User entered 'None (0)'	(b) (4), (b) (6) System	31 Aug 2020 12:43:29
	System	31 Aug 2020 12:43:29

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:43:01', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '884328c5-675d-4bb8-8f40-70d6a82fccd6' User entered 'None (0)'	(b) (4), (b) (6) System	31 Aug 2020 12:43:29
	System	31 Aug 2020 12:43:29

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:43:10', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '884328c5-675d-4bb8-8f40-70d6a82fccd6' User entered 'No (N)'	(b) (4), (b) (6) System	31 Aug 2020 12:43:29
	System	31 Aug 2020 12:43:29

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T08:43:27', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '884328c5-675d-4bb8-8f40-70d6a82fccd6' User entered '31 Aug 2020 08:43'	(b) (4), (b) (6) System	31 Aug 2020 12:43:29
	System	31 Aug 2020 12:43:29

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '30 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '31 Aug 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 5'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:29:47', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3f966-d482-4b4b-8bfe-47c6bd3b615e' User entered 'None (0)'	(b) (4), (b) (6) System	01 Sep 2020 01:30:06
	System	01 Sep 2020 01:30:06

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:29:14', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3f966-d482-4b4b-8bfe-47c6bd3b615e' User entered 'None (0)'	(b) (4), (b) (6) System	01 Sep 2020 01:30:06
	System	01 Sep 2020 01:30:06

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:29:19', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3f966-d482-4b4b-8bfe-47c6bd3b615e' User entered 'None (0)'	(b) (4), (b) (6) System	01 Sep 2020 01:30:06
	System	01 Sep 2020 01:30:06

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:29:23', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3f966-d482-4b4b-8bfe-47c6bd3b615e' User entered 'None (0)'	(b) (4), (b) (6) System	01 Sep 2020 01:30:06
	System	01 Sep 2020 01:30:06

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:29:27', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3f966-d482-4b4b-8bfe-47c6bd3b615e' User entered 'None (0)'	(b) (4), (b) (6) System	01 Sep 2020 01:30:06
	System	01 Sep 2020 01:30:06

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:29:31', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3f966-d482-4b4b-8bfe-47c6bd3b615e' User entered 'None (0)'	(b) (4), (b) (6) System	01 Sep 2020 01:30:06
	System	01 Sep 2020 01:30:06

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:29:41', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3f966-d482-4b4b-8bfe-47c6bd3b615e' User entered 'No (N)'	(b) (4), (b) (6) System	01 Sep 2020 01:30:06
	System	01 Sep 2020 01:30:06

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-08-31T21:30:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3f966-d482-4b4b-8bfe-47c6bd3b615e' User entered '31 Aug 2020 21:30'	(b) (4), (b) (6) System	01 Sep 2020 01:30:06
	System	01 Sep 2020 01:30:06

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '31 Aug 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '01 Sep 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 6'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:06:06', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'e3f5f77c-3565-43a9-a740-eb37e20b3775' User entered 'None (0)'	(b) (4), (b) (6) System	02 Sep 2020 02:06:44
	System	02 Sep 2020 02:06:44

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:06:10', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'e3f5f77c-3565-43a9-a740-eb37e20b3775' User entered 'None (0)'	(b) (4), (b) (6) System	02 Sep 2020 02:06:44
	System	02 Sep 2020 02:06:44

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:06:14', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'e3f5f77c-3565-43a9-a740-eb37e20b3775' User entered 'None (0)'	(b) (4), (b) (6) System	02 Sep 2020 02:06:44
	System	02 Sep 2020 02:06:44

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:06:18', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'e3f5f77c-3565-43a9-a740-eb37e20b3775' User entered 'None (0)'	(b) (4), (b) (6) System	02 Sep 2020 02:06:44
	System	02 Sep 2020 02:06:44

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:06:21', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'e3f5f77c-3565-43a9-a740-eb37e20b3775' User entered 'None (0)'	(b) (4), (b) (6) System	02 Sep 2020 02:06:44
	System	02 Sep 2020 02:06:44

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:06:25', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'e3f5f77c-3565-43a9-a740-eb37e20b3775' User entered 'None (0)'	(b) (4), (b) (6) System	02 Sep 2020 02:06:44
	System	02 Sep 2020 02:06:44

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:06:31', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'e3f5f77c-3565-43a9-a740-eb37e20b3775' User entered 'No (N)'	(b) (4), (b) (6) System	02 Sep 2020 02:06:44
	System	02 Sep 2020 02:06:44

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-01T22:06:42', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'e3f5f77c-3565-43a9-a740-eb37e20b3775' User entered '01 Sep 2020 22:06'	(b) (4), (b) (6) System	02 Sep 2020 02:06:44
	System	02 Sep 2020 02:06:44

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '01 Sep 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '02 Sep 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 7'	System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:29:25', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd1fbc96-bd31-4baa-a7bf-a25c1eedf328' User entered 'None (0)'	(b) (4), (b) (6) System	02 Sep 2020 23:29:57
	System	02 Sep 2020 23:29:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:29:28', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd1fbc96-bd31-4baa-a7bf-a25c1eedf328' User entered 'None (0)'	(b) (4), (b) (6) System	02 Sep 2020 23:29:57
	System	02 Sep 2020 23:29:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:29:31', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd1fbc96-bd31-4baa-a7bf-a25c1eedf328' User entered 'None (0)'	(b) (4), (b) (6) System	02 Sep 2020 23:29:57
	System	02 Sep 2020 23:29:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:29:35', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd1fbc96-bd31-4baa-a7bf-a25c1eedf328' User entered 'None (0)'	(b) (4), (b) (6) System	02 Sep 2020 23:29:57
	System	02 Sep 2020 23:29:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:29:38', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd1fbc96-bd31-4baa-a7bf-a25c1eedf328' User entered 'None (0)'	(b) (4), (b) (6) System	02 Sep 2020 23:29:57
	System	02 Sep 2020 23:29:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:29:41', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd1fbc96-bd31-4baa-a7bf-a25c1eedf328' User entered 'None (0)'	(b) (4), (b) (6) System	02 Sep 2020 23:29:57
	System	02 Sep 2020 23:29:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:29:45', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd1fbc96-bd31-4baa-a7bf-a25c1eedf328' User entered 'No (N)'	(b) (4), (b) (6) System	02 Sep 2020 23:29:57
	System	02 Sep 2020 23:29:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-02T19:29:53', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd1fbc96-bd31-4baa-a7bf-a25c1eedf328' User entered '02 Sep 2020 19:29'	(b) (4), (b) (6) System	02 Sep 2020 23:29:57
	System	02 Sep 2020 23:29:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '02 Sep 2020 12:00'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '03 Sep 2020 11:59'	(b) (4), (b) (6) System	27 Aug 2020 19:56:57

US3242231

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:08
User entered 'Yes (Y)'	Grace Newville (b) (4)	04 Sep 2020 18:06:11
	(b) (4)	

US3242231

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 15:01:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	10 Nov 2020 12:44:28
User entered '04 Sep 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Nov 2020 12:44:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:08
User entered '4 Sep 2020'	Grace Newville (b) (4)	04 Sep 2020 18:06:11
	(b) (4)	

US3242231

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:08
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	04 Sep 2020 18:06:11
	(b) (4)	

US3242231

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:08
User entered empty.	Grace Newville (b) (4)	04 Sep 2020 18:06:11
	(b) (4)	

US3242231

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:24
User entered 'Yes (Y)'	Grace Newville (b) (4)	04 Sep 2020 18:06:16
	(b) (4)	

US3242231

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
User entered 'I'	(b) (4), (b) (6)	04 Sep 2020 18:06:16
	System	

US3242231

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:33
User entered 'Yes (Y)'	Grace Newville (b) (4)	12 Sep 2020 01:16:33
	(b) (4)	

US3242231

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:33
User entered '11 Sep 2020'	Grace Newville (b) (4)	12 Sep 2020 01:16:33
	(b) (4)	

US3242231

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:33
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	12 Sep 2020 01:16:33
	(b) (4)	

US3242231

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:33
User entered empty.	Grace Newville (b) (4)	12 Sep 2020 01:16:33
	(b) (4)	

US3242231

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:40
User entered 'Yes (Y)'	Grace Newville (b) (4)	12 Sep 2020 01:16:25
	(b) (4)	

US3242231

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
User entered 'I'	System	12 Sep 2020 01:16:25

US3242231

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:51
User entered 'Yes (Y)'	Grace Newville (b) (4)	17 Sep 2020 22:26:07
	(b) (4)	

US3242231

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:51
User entered '17 Sep 2020'	Grace Newville (b) (4)	17 Sep 2020 22:26:07
	(b) (4)	

US3242231

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:51
User entered 'Contact Made (CONTACT MADE)'	Grace Newville (b) (4)	17 Sep 2020 22:26:07
	(b) (4)	

US3242231

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:52:51
User entered empty.	Grace Newville (b) (4)	17 Sep 2020 22:26:07
	(b) (4)	

US3242231

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:53:08
User entered 'Yes (Y)'	Grace Newville (b) (4)	17 Sep 2020 22:26:10
	(b) (4)	

US3242231

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
User entered 'I'	(b) (4), (b) (6) System	17 Sep 2020 22:26:10

US3242231

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Sep 2020 13:21:21
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '25 Sep 2020'	Erynn McKinley (b) (4)	25 Sep 2020 13:21:21
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	25 Sep 2020 13:21:21
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'VISIT2'	System	25 Sep 2020 13:21:21

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '25 Sep 2020'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '08:36' reason for change: Data Entry Error	Erynn McKinley (b) (4)	14 Dec 2020 16:56:59
	(b) (4)	
User entered '8:36'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User entered '25 Sep 2020 08:36'	System	14 Dec 2020 16:56:59
User entered '25 Sep 2020 8:36'	System	25 Sep 2020 14:58:55

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '97.3' F	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '62'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'bpm'	System	25 Sep 2020 14:58:55

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '16'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'breaths/min'	System	25 Sep 2020 14:58:55

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '116'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'mmHg'	(b) (4), (b) (6) System	25 Sep 2020 14:58:55

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '60'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:11:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'mmHg'	(b) (4), (b) (6) System	25 Sep 2020 14:58:55

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User accepted default value 'Post-Dose (POSTDOSE)'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '25 Sep 2020'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '10:19'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered '25 Sep 2020 10:19'	(b) (4), (b) (6)	25 Sep 2020 14:58:55
	System	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '97.6' F	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Oral (Oral)'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '64'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'bpm'	System	25 Sep 2020 14:58:55

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '16'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'breaths/min'	(b) (4), (b) (6) System	25 Sep 2020 14:58:55

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '118'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'mmHg'	(b) (4), (b) (6) System	25 Sep 2020 14:58:55

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '64'	Erynn McKinley (b) (4)	25 Sep 2020 14:58:55
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:11:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'mmHg'	(b) (4), (b) (6) System	25 Sep 2020 14:58:55

US3242231

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'No (N)'	Erynn McKinley (b) (4)	25 Sep 2020 13:21:32
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 13:21:32
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Sep 2020 13:49:12
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 13:49:12
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 13:49:12
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6)	25 Sep 2020 13:49:12
	System	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '25 Sep 2020'	Erynn McKinley (b) (4)	25 Sep 2020 13:49:12
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '09:46' reason for change: Data Entry Error	Erynn McKinley (b) (4)	14 Dec 2020 16:58:03
	(b) (4)	
User entered '9:46'	Erynn McKinley (b) (4)	25 Sep 2020 13:49:12
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User entered '25 Sep 2020 09:46'	System	14 Dec 2020 16:58:03
User entered '25 Sep 2020 9:46'	System	25 Sep 2020 13:49:12

US3242231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Left Arm (LEFT ARM)'	Erynn McKinley (b) (4)	25 Sep 2020 13:49:12
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'ONCE'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:11:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Sep 2020 13:21:48
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '25 Sep 2020'	Erynn McKinley (b) (4)	25 Sep 2020 13:21:48
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '09:13' reason for change: Data Entry Error	Erynn McKinley (b) (4)	14 Dec 2020 16:57:40
	(b) (4)	
User entered '9:13'	Erynn McKinley (b) (4)	25 Sep 2020 13:21:48
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User entered '25 Sep 2020 09:13'	System	14 Dec 2020 16:57:40
User entered '25 Sep 2020 9:13'	System	25 Sep 2020 13:21:48

US3242231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:11:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '25 Sep 2020'	Erynn McKinley (b) (4)	25 Sep 2020 13:24:32
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Erynn McKinley (b) (4)	25 Sep 2020 13:24:32
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Sep 2020 13:24:32
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '09:10' reason for change: Data Entry Error	Erynn McKinley (b) (4)	14 Dec 2020 16:57:20
	(b) (4)	
User entered '9:10'	Erynn McKinley (b) (4)	25 Sep 2020 13:24:32
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User entered '25 Sep 2020 09:10'	System	14 Dec 2020 16:57:20
User entered '25 Sep 2020 9:10'	System	25 Sep 2020 13:24:32

US3242231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:06

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Erynn McKinley (b) (4)	25 Sep 2020 13:24:32
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'No (N)'	Erynn McKinley (b) (4)	25 Sep 2020 13:24:32
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:06

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered empty.	Erynn McKinley (b) (4)	25 Sep 2020 13:24:32
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 13:24:32
	System	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	25 Sep 2020 13:24:36
	(b) (4)	

US3242231

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'I'	System	25 Sep 2020 13:24:36

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:21:49', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '00b7465a-40d8-413c-8d13-bc24bdc901c8' User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Sep 2020 14:22:26
	System	25 Sep 2020 14:22:26

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:21:59', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '00b7465a-40d8-413c-8d13-bc24bdc901c8' User entered '97.6'	(b) (4), (b) (6) System	25 Sep 2020 14:22:26
	System	25 Sep 2020 14:22:26

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:22:12', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '00b7465a-40d8-413c-8d13-bc24bdc901c8' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 14:22:26
	System	25 Sep 2020 14:22:26

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:22:24', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '00b7465a-40d8-413c-8d13-bc24bdc901c8' User entered '25 Sep 2020 10:22'	(b) (4), (b) (6) System	25 Sep 2020 14:22:26
	System	25 Sep 2020 14:22:26

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '25 Sep 2020 10:06'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '25 Sep 2020 12:36'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:45:44', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'dd010e5a-febd-4292-8ec0-205997d0b3d1' User entered 'Yes (Y)'	(b) (4), (b) (6) System	26 Sep 2020 03:47:24
	System	26 Sep 2020 03:47:24

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:46:38', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'dd010e5a-febd-4292-8ec0-205997d0b3d1' User entered '97.5'	(b) (4), (b) (6) System	26 Sep 2020 03:47:24
	System	26 Sep 2020 03:47:24

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:46:49', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'dd010e5a-febd-4292-8ec0-205997d0b3d1' User entered 'Yes (Y)'	(b) (4), (b) (6) System	26 Sep 2020 03:47:24
	System	26 Sep 2020 03:47:24

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject was contacted and conmed recorded' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 10:21:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Grace Newville (b) (4) (b) (4)	29 Sep 2020 12:30:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:47:06', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'dd010e5a-febd-4292-8ec0-205997d0b3d1'	System	26 Sep 2020 03:47:24
User entered '1'	System	26 Sep 2020 03:47:24

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:47:06', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'dd010e5a-febd-4292-8ec0-205997d0b3d1' User entered '0'	(b) (4), (b) (6) System	26 Sep 2020 03:47:24
	System	26 Sep 2020 03:47:24

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:47:23', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'dd010e5a-febd-4292-8ec0-205997d0b3d1' User entered '25 Sep 2020 23:47'	(b) (4), (b) (6) System	26 Sep 2020 03:47:24
	System	26 Sep 2020 03:47:24

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '25 Sep 2020 13:31'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 2'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:14:29', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '329d22d6-1172-4914-a2b2-bd4ecfa0686f' User entered 'Yes (Y)'	(b) (4), (b) (6) System	26 Sep 2020 21:15:08
	System	26 Sep 2020 21:15:08

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:14:45', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '329d22d6-1172-4914-a2b2-bd4ecfa0686f' User entered '98.7'	(b) (4), (b) (6) System	26 Sep 2020 21:15:08
	System	26 Sep 2020 21:15:08

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:14:55', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '329d22d6-1172-4914-a2b2-bd4ecfa0686f' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 21:15:08
	System	26 Sep 2020 21:15:08

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:15:05', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '329d22d6-1172-4914-a2b2-bd4ecfa0686f' User entered '26 Sep 2020 17:15'	(b) (4), (b) (6) System	26 Sep 2020 21:15:08
	System	26 Sep 2020 21:15:08

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 3'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:35:01', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'de462060-5773-40fb-9fad-04362dc1dbb1' User entered 'Yes (Y)'	(b) (4), (b) (6) System	28 Sep 2020 01:35:42
	System	28 Sep 2020 01:35:42

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:35:15', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'de462060-5773-40fb-9fad-04362dc1dbb1' User entered '96.8'	(b) (4), (b) (6) System	28 Sep 2020 01:35:42
	System	28 Sep 2020 01:35:42

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:35:24', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'de462060-5773-40fb-9fad-04362dc1dbb1' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 01:35:42
	System	28 Sep 2020 01:35:42

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:35:39', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'de462060-5773-40fb-9fad-04362dc1dbb1' User entered '27 Sep 2020 21:35'	(b) (4), (b) (6) System	28 Sep 2020 01:35:42
	System	28 Sep 2020 01:35:42

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 4'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:49:57', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '341e0d97-2d21-477f-8699-692a679403b7' User entered 'Yes (Y)'	(b) (4), (b) (6) System	28 Sep 2020 22:50:35
	System	28 Sep 2020 22:50:35

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:50:05', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '341e0d97-2d21-477f-8699-692a679403b7' User entered '98.2'	(b) (4), (b) (6) System	28 Sep 2020 22:50:35
	System	28 Sep 2020 22:50:35

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:50:11', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '341e0d97-2d21-477f-8699-692a679403b7'	(b) (4), (b) (6)	
User entered 'No (N)'	System	28 Sep 2020 22:50:35

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:50:30', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '341e0d97-2d21-477f-8699-692a679403b7' User entered '28 Sep 2020 18:50'	(b) (4), (b) (6) System	28 Sep 2020 22:50:35
	System	28 Sep 2020 22:50:35

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 5'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:31:17', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '5947ed43-9309-481c-8a7a-0ed04c530221' User entered 'Yes (Y)'	(b) (4), (b) (6) System	29 Sep 2020 21:31:44
	System	29 Sep 2020 21:31:44

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:31:28', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '5947ed43-9309-481c-8a7a-0ed04c530221' User entered '97.0'	(b) (4), (b) (6) System	29 Sep 2020 21:31:44
	System	29 Sep 2020 21:31:44

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:31:35', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '5947ed43-9309-481c-8a7a-0ed04c530221'	(b) (4), (b) (6)	
	System	29 Sep 2020 21:31:44
User entered 'No (N)'	System	29 Sep 2020 21:31:44

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:31:41', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '5947ed43-9309-481c-8a7a-0ed04c530221' User entered '29 Sep 2020 17:31'	(b) (4), (b) (6) System	29 Sep 2020 21:31:44
	System	29 Sep 2020 21:31:44

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 6'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:03:32', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd468cf79-0470-483b-a666-f920906a0888' User entered 'Yes (Y)'	(b) (4), (b) (6) System	01 Oct 2020 01:04:10
	System	01 Oct 2020 01:04:10

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:03:52', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd468cf79-0470-483b-a666-f920906a0888' User entered '96.9'	(b) (4), (b) (6) System	01 Oct 2020 01:04:10
	System	01 Oct 2020 01:04:10

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:03:59', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd468cf79-0470-483b-a666-f920906a0888'	(b) (4), (b) (6)	
	System	01 Oct 2020 01:04:10
User entered 'No (N)'	System	01 Oct 2020 01:04:10

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:04:06', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd468cf79-0470-483b-a666-f920906a0888' User entered '30 Sep 2020 21:04'	(b) (4), (b) (6) System	01 Oct 2020 01:04:10
	System	01 Oct 2020 01:04:10

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 7'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:36:01', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '5a3d324c-905d-4f45-99f9-663a524bfab1' User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 00:36:27
	System	02 Oct 2020 00:36:27

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:36:13', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '5a3d324c-905d-4f45-99f9-663a524bfab1' User entered '97.0'	(b) (4), (b) (6) System	02 Oct 2020 00:36:27
	System	02 Oct 2020 00:36:27

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:36:19', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '5a3d324c-905d-4f45-99f9-663a524bfab1' User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 00:36:27
	System	02 Oct 2020 00:36:27

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:36:26', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '5a3d324c-905d-4f45-99f9-663a524bfab1' User entered '01 Oct 2020 20:36'	(b) (4), (b) (6) System	02 Oct 2020 00:36:27
	System	02 Oct 2020 00:36:27

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '01 Oct 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:22:34', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'f0eaea1f-aa8e-4881-ac93-31d2d42c00a2'	(b) (4), (b) (6)	
	System	25 Sep 2020 14:23:01
User entered 'None (1)'	System	25 Sep 2020 14:23:01

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:22:44', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'f0eaea1f-aa8e-4881-ac93-31d2d42c00a2' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 14:23:01
	System	25 Sep 2020 14:23:01

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:22:49', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'f0eaea1f-aa8e-4881-ac93-31d2d42c00a2' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 14:23:01
	System	25 Sep 2020 14:23:01

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:22:54', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'f0eaea1f-aa8e-4881-ac93-31d2d42c00a2'	(b) (4), (b) (6)	
User entered 'None (1)'	System	25 Sep 2020 14:23:01

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:22:59', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'f0eaea1f-aa8e-4881-ac93-31d2d42c00a2' User entered '25 Sep 2020 10:22'	(b) (4), (b) (6) System	25 Sep 2020 14:23:01
	System	25 Sep 2020 14:23:01

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '25 Sep 2020 10:06'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '25 Sep 2020 12:36'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:49:41', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '1dfb2114-6711-472b-ba2b-334b4586ee49'	(b) (4), (b) (6)	
	System	26 Sep 2020 03:50:05
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 03:50:05

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:47:43', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '1dfb2114-6711-472b-ba2b-334b4586ee49' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 03:50:05
	System	26 Sep 2020 03:50:05

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:47:48', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '1dfb2114-6711-472b-ba2b-334b4586ee49' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 03:50:05
	System	26 Sep 2020 03:50:05

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:47:52', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '1dfb2114-6711-472b-ba2b-334b4586ee49'	(b) (4), (b) (6)	
User entered 'None (1)'	System	26 Sep 2020 03:50:05

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:50:02', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '1dfb2114-6711-472b-ba2b-334b4586ee49' User entered '25 Sep 2020 23:50'	(b) (4), (b) (6) System	26 Sep 2020 03:50:05
	System	26 Sep 2020 03:50:05

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '25 Sep 2020 13:31'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 2'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:16:16', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8a8674d5-a905-4033-b437-d9e60ea5d599'	(b) (4), (b) (6)	26 Sep 2020 21:17:03
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 21:17:03

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:16:21', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8a8674d5-a905-4033-b437-d9e60ea5d599' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 21:17:03
	System	26 Sep 2020 21:17:03

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:16:26', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8a8674d5-a905-4033-b437-d9e60ea5d599' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 21:17:03
	System	26 Sep 2020 21:17:03

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:16:32', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8a8674d5-a905-4033-b437-d9e60ea5d599'	(b) (4), (b) (6)	
User entered 'None (1)'	System	26 Sep 2020 21:17:03

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:16:59', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8a8674d5-a905-4033-b437-d9e60ea5d599' User entered '26 Sep 2020 17:16'	(b) (4), (b) (6) System	26 Sep 2020 21:17:03
	System	26 Sep 2020 21:17:03

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 3'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:35:53', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '0635858b-9609-42a1-985e-c101e84a78b1' User entered 'None (1)'	(b) (4), (b) (6) System	28 Sep 2020 01:36:25
	System	28 Sep 2020 01:36:25

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:35:59', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '0635858b-9609-42a1-985e-c101e84a78b1' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 01:36:25
	System	28 Sep 2020 01:36:25

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:36:04', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '0635858b-9609-42a1-985e-c101e84a78b1' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 01:36:25
	System	28 Sep 2020 01:36:25

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:36:12', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '0635858b-9609-42a1-985e-c101e84a78b1' User entered 'None (1)'	(b) (4), (b) (6) System	28 Sep 2020 01:36:25
	System	28 Sep 2020 01:36:25

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:36:21', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '0635858b-9609-42a1-985e-c101e84a78b1' User entered '27 Sep 2020 21:36'	(b) (4), (b) (6) System	28 Sep 2020 01:36:25
	System	28 Sep 2020 01:36:25

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 4'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:50:45', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '35c181e0-ddf9-4781-9fad-90f7b9a15535' User entered 'None (1)'	(b) (4), (b) (6) System	28 Sep 2020 22:51:19
	System	28 Sep 2020 22:51:19

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:50:50', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '35c181e0-ddf9-4781-9fad-90f7b9a15535' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 22:51:19
	System	28 Sep 2020 22:51:19

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:50:59', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '35c181e0-ddf9-4781-9fad-90f7b9a15535' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 22:51:19
	System	28 Sep 2020 22:51:19

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:51:06', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '35c181e0-ddf9-4781-9fad-90f7b9a15535' User entered 'None (1)'	(b) (4), (b) (6) System	28 Sep 2020 22:51:19
	System	28 Sep 2020 22:51:19

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:51:17', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '35c181e0-ddf9-4781-9fad-90f7b9a15535' User entered '28 Sep 2020 18:51'	(b) (4), (b) (6) System	28 Sep 2020 22:51:19
	System	28 Sep 2020 22:51:19

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 5'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:31:50', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '842b049d-8963-4940-8b2a-93616923ee65'	(b) (4), (b) (6)	
	System	29 Sep 2020 21:32:28
User entered 'None (1)'	System	29 Sep 2020 21:32:28

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:32:02', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '842b049d-8963-4940-8b2a-93616923ee65'	(b) (4), (b) (6)	
User entered 'No (N)'	System	29 Sep 2020 21:32:28

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:32:08', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '842b049d-8963-4940-8b2a-93616923ee65'	(b) (4), (b) (6)	
User entered 'No (N)'	System	29 Sep 2020 21:32:28

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:32:16', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '842b049d-8963-4940-8b2a-93616923ee65'	(b) (4), (b) (6)	
	System	29 Sep 2020 21:32:28
User entered 'None (1)'	System	29 Sep 2020 21:32:28

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:32:26', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '842b049d-8963-4940-8b2a-93616923ee65' User entered '29 Sep 2020 17:32'	(b) (4), (b) (6) System	29 Sep 2020 21:32:28
	System	29 Sep 2020 21:32:28

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 6'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:04:13', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '142090c4-1be1-499f-bc9d-c20f8aaaeceb' User entered 'None (1)'	(b) (4), (b) (6) System	01 Oct 2020 01:04:44
	System	01 Oct 2020 01:04:44

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:04:20', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '142090c4-1be1-499f-bc9d-c20f8aaaceb' User entered 'No (N)'	(b) (4), (b) (6) System	01 Oct 2020 01:04:44
	System	01 Oct 2020 01:04:44

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:04:25', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '142090c4-1be1-499f-bc9d-c20f8aaaceb' User entered 'No (N)'	(b) (4), (b) (6) System	01 Oct 2020 01:04:44
	System	01 Oct 2020 01:04:44

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:04:34', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '142090c4-1be1-499f-bc9d-c20f8aaaeceb' User entered 'None (1)'	(b) (4), (b) (6) System	01 Oct 2020 01:04:44
	System	01 Oct 2020 01:04:44

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:04:41', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '142090c4-1be1-499f-bc9d-c20f8aaaeceb' User entered '30 Sep 2020 21:04'	(b) (4), (b) (6) System	01 Oct 2020 01:04:44
	System	01 Oct 2020 01:04:44

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 7'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:36:32', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '73d331ac-10a4-4af1-9028-2ed0715d74c6' User entered 'None (1)'	(b) (4), (b) (6) System	02 Oct 2020 00:37:05
	System	02 Oct 2020 00:37:05

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:36:38', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '73d331ac-10a4-4af1-9028-2ed0715d74c6' User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 00:37:05
	System	02 Oct 2020 00:37:05

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:36:46', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '73d331ac-10a4-4af1-9028-2ed0715d74c6' User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 00:37:05
	System	02 Oct 2020 00:37:05

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:36:55', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '73d331ac-10a4-4af1-9028-2ed0715d74c6' User entered 'None (1)'	(b) (4), (b) (6) System	02 Oct 2020 00:37:05
	System	02 Oct 2020 00:37:05

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:37:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '73d331ac-10a4-4af1-9028-2ed0715d74c6' User entered '01 Oct 2020 20:37'	(b) (4), (b) (6) System	02 Oct 2020 00:37:05
	System	02 Oct 2020 00:37:05

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '01 Oct 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:23:04', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd6cd8f97-f344-4fde-889f-d906ea5120b0' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 14:23:41
	System	25 Sep 2020 14:23:41

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:23:08', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd6cd8f97-f344-4fde-889f-d906ea5120b0' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 14:23:41
	System	25 Sep 2020 14:23:41

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:23:12', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd6cd8f97-f344-4fde-889f-d906ea5120b0' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 14:23:41
	System	25 Sep 2020 14:23:41

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:23:16', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd6cd8f97-f344-4fde-889f-d906ea5120b0' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 14:23:41
	System	25 Sep 2020 14:23:41

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:23:20', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd6cd8f97-f344-4fde-889f-d906ea5120b0' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 14:23:41
	System	25 Sep 2020 14:23:41

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:23:23', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd6cd8f97-f344-4fde-889f-d906ea5120b0' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 14:23:41
	System	25 Sep 2020 14:23:41

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:23:33', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd6cd8f97-f344-4fde-889f-d906ea5120b0' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 14:23:41
	System	25 Sep 2020 14:23:41

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T10:23:37', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd6cd8f97-f344-4fde-889f-d906ea5120b0' User entered '25 Sep 2020 10:23'	(b) (4), (b) (6) System	25 Sep 2020 14:23:41
	System	25 Sep 2020 14:23:41

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '25 Sep 2020 10:06'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '25 Sep 2020 12:36'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:50:17', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '799b1f52-c5d8-459d-b499-17912797ab8d' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 03:51:15
	System	26 Sep 2020 03:51:15

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:50:22', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '799b1f52-c5d8-459d-b499-17912797ab8d' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 03:51:15
	System	26 Sep 2020 03:51:15

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:50:31', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '799b1f52-c5d8-459d-b499-17912797ab8d' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 03:51:15
	System	26 Sep 2020 03:51:15

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:50:37', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '799b1f52-c5d8-459d-b499-17912797ab8d' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 03:51:15
	System	26 Sep 2020 03:51:15

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:50:41', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '799b1f52-c5d8-459d-b499-17912797ab8d' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 03:51:15
	System	26 Sep 2020 03:51:15

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:50:45', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '799b1f52-c5d8-459d-b499-17912797ab8d' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 03:51:15
	System	26 Sep 2020 03:51:15

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:50:59', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '799b1f52-c5d8-459d-b499-17912797ab8d' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 03:51:15
	System	26 Sep 2020 03:51:15

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-25T23:51:14', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '799b1f52-c5d8-459d-b499-17912797ab8d' User entered '25 Sep 2020 23:51'	(b) (4), (b) (6) System	26 Sep 2020 03:51:15
	System	26 Sep 2020 03:51:15

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '25 Sep 2020 13:31'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 2'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:17:12', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '75ee4255-413d-48ab-b255-7c5588f4e444'	(b) (4), (b) (6)	
	System	26 Sep 2020 21:18:04
User entered 'None (0)'	System	26 Sep 2020 21:18:04

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:17:15', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '75ee4255-413d-48ab-b255-7c5588f4e444' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 21:18:04
	System	26 Sep 2020 21:18:04

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:17:21', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '75ee4255-413d-48ab-b255-7c5588f4e444'	(b) (4), (b) (6)	
User entered 'None (0)'	System	26 Sep 2020 21:18:04

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:17:27', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '75ee4255-413d-48ab-b255-7c5588f4e444' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 21:18:04
	System	26 Sep 2020 21:18:04

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:17:31', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '75ee4255-413d-48ab-b255-7c5588f4e444' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 21:18:04
	System	26 Sep 2020 21:18:04

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:17:35', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '75ee4255-413d-48ab-b255-7c5588f4e444' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 21:18:04
	System	26 Sep 2020 21:18:04

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:17:48', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '75ee4255-413d-48ab-b255-7c5588f4e444'	(b) (4), (b) (6)	
	System	26 Sep 2020 21:18:04
User entered 'No (N)'	System	26 Sep 2020 21:18:04

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-26T17:18:02', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '75ee4255-413d-48ab-b255-7c5588f4e444'	(b) (4), (b) (6)	
	System	26 Sep 2020 21:18:04
User entered '26 Sep 2020 17:18'	System	26 Sep 2020 21:18:04

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 3'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:36:28', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '31575863-0681-40e1-822a-b48c59aed90b' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 01:37:07
	System	28 Sep 2020 01:37:07

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:36:31', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '31575863-0681-40e1-822a-b48c59aed90b' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 01:37:07
	System	28 Sep 2020 01:37:07

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:36:34', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '31575863-0681-40e1-822a-b48c59aed90b' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 01:37:07
	System	28 Sep 2020 01:37:07

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:36:36', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '31575863-0681-40e1-822a-b48c59aed90b' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 01:37:07
	System	28 Sep 2020 01:37:07

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:36:39', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '31575863-0681-40e1-822a-b48c59aed90b' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 01:37:07
	System	28 Sep 2020 01:37:07

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:36:43', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '31575863-0681-40e1-822a-b48c59aed90b' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 01:37:07
	System	28 Sep 2020 01:37:07

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:36:52', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '31575863-0681-40e1-822a-b48c59aed90b' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 01:37:07
	System	28 Sep 2020 01:37:07

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-27T21:37:01', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '31575863-0681-40e1-822a-b48c59aed90b' User entered '27 Sep 2020 21:37'	(b) (4), (b) (6) System	28 Sep 2020 01:37:07
	System	28 Sep 2020 01:37:07

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 4'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:51:30', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b5c12635-43f4-4e76-b0d6-42b59f1fb8cc' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 22:52:09
	System	28 Sep 2020 22:52:09

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:51:33', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b5c12635-43f4-4e76-b0d6-42b59f1fb8cc' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 22:52:09
	System	28 Sep 2020 22:52:09

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:51:36', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b5c12635-43f4-4e76-b0d6-42b59f1fb8cc' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 22:52:09
	System	28 Sep 2020 22:52:09

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:51:42', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b5c12635-43f4-4e76-b0d6-42b59f1fb8cc' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 22:52:09
	System	28 Sep 2020 22:52:09

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:51:48', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b5c12635-43f4-4e76-b0d6-42b59f1fb8cc' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 22:52:09
	System	28 Sep 2020 22:52:09

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:51:51', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b5c12635-43f4-4e76-b0d6-42b59f1fb8cc' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 22:52:09
	System	28 Sep 2020 22:52:09

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:51:57', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b5c12635-43f4-4e76-b0d6-42b59f1fb8cc' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 22:52:09
	System	28 Sep 2020 22:52:09

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-28T18:52:07', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b5c12635-43f4-4e76-b0d6-42b59f1fb8cc' User entered '28 Sep 2020 18:52'	(b) (4), (b) (6) System	28 Sep 2020 22:52:09
	System	28 Sep 2020 22:52:09

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 5'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:32:36', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '551bbc47-2d5e-45ce-8acc-e703d3270dab' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 21:33:20
	System	29 Sep 2020 21:33:20

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:32:40', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '551bbc47-2d5e-45ce-8acc-e703d3270dab' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 21:33:20
	System	29 Sep 2020 21:33:20

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:32:44', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '551bbc47-2d5e-45ce-8acc-e703d3270dab' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 21:33:20
	System	29 Sep 2020 21:33:20

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:32:51', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '551bbc47-2d5e-45ce-8acc-e703d3270dab' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 21:33:20
	System	29 Sep 2020 21:33:20

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:32:56', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '551bbc47-2d5e-45ce-8acc-e703d3270dab' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 21:33:20
	System	29 Sep 2020 21:33:20

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:33:04', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '551bbc47-2d5e-45ce-8acc-e703d3270dab' User entered 'None (0)'	(b) (4), (b) (6) System	29 Sep 2020 21:33:20
	System	29 Sep 2020 21:33:20

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:33:11', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '551bbc47-2d5e-45ce-8acc-e703d3270dab' User entered 'No (N)'	(b) (4), (b) (6) System	29 Sep 2020 21:33:20
	System	29 Sep 2020 21:33:20

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-29T17:33:19', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '551bbc47-2d5e-45ce-8acc-e703d3270dab' User entered '29 Sep 2020 17:33'	(b) (4), (b) (6) System	29 Sep 2020 21:33:20
	System	29 Sep 2020 21:33:20

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 6'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:04:49', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3d64b-b3b1-462c-aab9-432045514c81' User entered 'None (0)'	(b) (4), (b) (6) System	01 Oct 2020 01:05:22
	System	01 Oct 2020 01:05:22

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:04:53', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3d64b-b3b1-462c-aab9-432045514c81' User entered 'None (0)'	(b) (4), (b) (6) System	01 Oct 2020 01:05:22
	System	01 Oct 2020 01:05:22

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:04:55', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3d64b-b3b1-462c-aab9-432045514c81' User entered 'None (0)'	(b) (4), (b) (6) System	01 Oct 2020 01:05:22
	System	01 Oct 2020 01:05:22

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:04:58', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3d64b-b3b1-462c-aab9-432045514c81' User entered 'None (0)'	(b) (4), (b) (6) System	01 Oct 2020 01:05:22
	System	01 Oct 2020 01:05:22

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:05:02', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3d64b-b3b1-462c-aab9-432045514c81' User entered 'None (0)'	(b) (4), (b) (6) System	01 Oct 2020 01:05:22
	System	01 Oct 2020 01:05:22

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:05:05', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3d64b-b3b1-462c-aab9-432045514c81' User entered 'None (0)'	(b) (4), (b) (6) System	01 Oct 2020 01:05:22
	System	01 Oct 2020 01:05:22

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:05:12', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3d64b-b3b1-462c-aab9-432045514c81' User entered 'No (N)'	(b) (4), (b) (6) System	01 Oct 2020 01:05:22
	System	01 Oct 2020 01:05:22

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-09-30T21:05:19', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'b4e3d64b-b3b1-462c-aab9-432045514c81' User entered '30 Sep 2020 21:05'	(b) (4), (b) (6) System	01 Oct 2020 01:05:22
	System	01 Oct 2020 01:05:22

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	25 Sep 2020 13:49:12
User entered 'Day 7'	System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:37:08', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '79401e74-8aa1-4730-9ead-c5cd782a118f' User entered 'None (0)'	(b) (4), (b) (6) System	02 Oct 2020 00:37:44
	System	02 Oct 2020 00:37:44

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:37:12', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '79401e74-8aa1-4730-9ead-c5cd782a118f' User entered 'None (0)'	(b) (4), (b) (6) System	02 Oct 2020 00:37:44
	System	02 Oct 2020 00:37:44

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:37:14', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '79401e74-8aa1-4730-9ead-c5cd782a118f' User entered 'None (0)'	(b) (4), (b) (6) System	02 Oct 2020 00:37:44
	System	02 Oct 2020 00:37:44

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:37:17', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '79401e74-8aa1-4730-9ead-c5cd782a118f' User entered 'None (0)'	(b) (4), (b) (6) System	02 Oct 2020 00:37:44
	System	02 Oct 2020 00:37:44

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:37:21', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '79401e74-8aa1-4730-9ead-c5cd782a118f' User entered 'None (0)'	(b) (4), (b) (6) System	02 Oct 2020 00:37:44
	System	02 Oct 2020 00:37:44

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:37:24', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '79401e74-8aa1-4730-9ead-c5cd782a118f' User entered 'None (0)'	(b) (4), (b) (6) System	02 Oct 2020 00:37:44
	System	02 Oct 2020 00:37:44

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:37:29', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '79401e74-8aa1-4730-9ead-c5cd782a118f' User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 00:37:44
	System	02 Oct 2020 00:37:44

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-01T20:37:38', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '79401e74-8aa1-4730-9ead-c5cd782a118f' User entered '01 Oct 2020 20:37'	(b) (4), (b) (6) System	02 Oct 2020 00:37:44
	System	02 Oct 2020 00:37:44

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '01 Oct 2020 12:00'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:11:06

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	25 Sep 2020 13:49:12

US3242231

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Oct 2020 15:25:17
	(b) (4)	

US3242231

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered '2 Oct 2020'	Erynn McKinley (b) (4)	05 Oct 2020 15:25:17
	(b) (4)	

US3242231

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	05 Oct 2020 15:25:17
	(b) (4)	

US3242231

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered empty.	Erynn McKinley (b) (4)	05 Oct 2020 15:25:17
	(b) (4)	

US3242231

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	05 Oct 2020 15:25:23
	(b) (4)	

US3242231

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
User entered 'I'	(b) (4), (b) (6)	05 Oct 2020 15:25:23
	System	

US3242231

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	19 Oct 2020 14:29:14
	(b) (4)	

US3242231

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered '12 Oct 2020'	Erynn McKinley (b) (4)	19 Oct 2020 14:29:14
	(b) (4)	

US3242231

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	19 Oct 2020 14:29:14
	(b) (4)	

US3242231

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered empty.	Erynn McKinley (b) (4)	19 Oct 2020 14:29:14
	(b) (4)	

US3242231

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	19 Oct 2020 14:29:18
	(b) (4)	

US3242231

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
User entered 'I'	(b) (4), (b) (6) System	19 Oct 2020 14:29:18

US3242231

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	22 Oct 2020 22:36:47

US3242231

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '19 Oct 2020'	Donna Toepfer (b) (4)	22 Oct 2020 22:36:47

US3242231

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Contact Made (CONTACT MADE)'	Donna Toepfer (b) (4)	22 Oct 2020 22:36:47

US3242231

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:36:47

US3242231

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	22 Oct 2020 22:37:11

US3242231

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
User entered 'I'	(b) (4), (b) (6) System	22 Oct 2020 22:37:11

US3242231

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	22 Oct 2020 22:37:21

US3242231

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '22 Oct 2020'	Donna Toepfer (b) (4)	22 Oct 2020 22:37:21

US3242231

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	22 Oct 2020 22:37:21

US3242231

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'VISIT3'	System	22 Oct 2020 22:37:21

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	22 Oct 2020 22:38:03

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '22 Oct 2020'	Donna Toepfer (b) (4)	22 Oct 2020 22:38:03

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '09:02'	Donna Toepfer (b) (4)	22 Oct 2020 22:38:03

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered '22 Oct 2020 09:02'	(b) (4), (b) (6)	22 Oct 2020 22:38:03
	System	

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '97.0' F	Donna Toepfer (b) (4)	22 Oct 2020 22:38:03

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Oral (Oral)'	Donna Toepfer (b) (4)	22 Oct 2020 22:38:03

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:38:03

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '60'	Donna Toepfer (b) (4)	22 Oct 2020 22:38:03

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'bpm'	System	22 Oct 2020 22:38:03

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '16'	Donna Toepfer (b) (4)	22 Oct 2020 22:38:03

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'breaths/min'	(b) (4), (b) (6)	22 Oct 2020 22:38:03
	System	

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '128'	Donna Toepfer (b) (4)	22 Oct 2020 22:38:03

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'mmHg'	(b) (4), (b) (6)	22 Oct 2020 22:38:03
	System	

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '82'	Donna Toepfer (b) (4)	22 Oct 2020 22:38:03

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'mmHg'	(b) (4), (b) (6)	22 Oct 2020 22:38:03
	System	

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	

US3242231

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	

US3242231

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Oct 2020 22:38:16

US3242231

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:38:16

US3242231

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	22 Oct 2020 22:38:33

US3242231

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '22 Oct 2020'	Donna Toepfer (b) (4)	22 Oct 2020 22:38:33

US3242231

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '09:30'	Donna Toepfer (b) (4)	22 Oct 2020 22:38:33

US3242231

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered '22 Oct 2020 09:30'	(b) (4), (b) (6)	22 Oct 2020 22:38:33
	System	

US3242231

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	22 Oct 2020 22:38:39

US3242231

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:22
User entered 'I'	(b) (4), (b) (6)	22 Oct 2020 22:38:39
	System	

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 64'	System	27 Aug 2020 19:56:57

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-27T07:45:08', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '977dd452-7031-4606-a71a-df83fd7f5bb5'	(b) (4), (b) (6)	
	System	27 Oct 2020 11:45:44
User entered 'No (N)'	System	27 Oct 2020 11:45:44

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-27T07:45:19', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '977dd452-7031-4606-a71a-df83fd7f5bb5'	(b) (4), (b) (6)	
	System	27 Oct 2020 11:45:44
User entered 'No (N)'	System	27 Oct 2020 11:45:44

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-10-27T07:45:40', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '977dd452-7031-4606-a71a-df83fd7f5bb5' User entered '27 Oct 2020 07:45:40'	(b) (4), (b) (6) System	27 Oct 2020 11:45:44
	System	27 Oct 2020 11:45:44

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 19:56:57

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 19:56:57

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 71'	System	27 Aug 2020 19:56:57

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04
Data entry locked.	System	27 Aug 2020 19:56:57
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 19:56:57

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:48:04
Data entry locked.	System	27 Aug 2020 19:56:57
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 19:56:57

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered 'Day 78'	System	27 Aug 2020 19:56:57

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-11-10T15:50:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '7a519451-4e40-4b53-8d85-c77755bc4a4a'	(b) (4), (b) (6)	
User entered 'No (N)'	System	10 Nov 2020 20:51:07

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-11-10T15:50:16', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '7a519451-4e40-4b53-8d85-c77755bc4a4a'	(b) (4), (b) (6)	
User entered 'No (N)'	System	10 Nov 2020 20:51:07

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-11-10T15:51:02', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '7a519451-4e40-4b53-8d85-c77755bc4a4a' User entered '10 Nov 2020 15:51:02'	(b) (4), (b) (6) System	10 Nov 2020 20:51:07
	System	10 Nov 2020 20:51:07

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 19:56:57

US3242231

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:22:10
	(b) (4), (b) (6)	
Data entry locked.	System	27 Aug 2020 19:56:57
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 19:56:57

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-11-23T11:30:31', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '1ad7637b-3c74-40b6-aedf-e96af54fd5f3'	System	23 Nov 2020 16:31:28
User entered 'No (N)'	System	23 Nov 2020 16:31:28

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-11-23T11:30:50', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '1ad7637b-3c74-40b6-aedf-e96af54fd5f3'	System	23 Nov 2020 16:31:28
User entered 'No (N)'	System	23 Nov 2020 16:31:28

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-11-23T11:31:26', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '1ad7637b-3c74-40b6-aedf-e96af54fd5f3'	System	23 Nov 2020 16:31:28
User entered '23 Nov 2020 11:31:26'	System	23 Nov 2020 16:31:28

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-12-01T22:24:30', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'f78b78eb-d9da-485d-bb0a-532031349b9b' User entered 'No (N)'	System	02 Dec 2020 03:24:55
	System	02 Dec 2020 03:24:55

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-12-01T22:24:42', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'f78b78eb-d9da-485d-bb0a-532031349b9b'	System	02 Dec 2020 03:24:55
User entered 'No (N)'	System	02 Dec 2020 03:24:55

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-12-01T22:24:52', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'f78b78eb-d9da-485d-bb0a-532031349b9b' User entered '01 Dec 2020 22:24:52'	System	02 Dec 2020 03:24:55
	System	02 Dec 2020 03:24:55

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-12-08T17:42:37', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'fbfc049e-1393-4320-ad5d-2c1f7a1733f9'	System	08 Dec 2020 22:42:51
User entered 'No (N)'	System	08 Dec 2020 22:42:51

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-12-08T17:42:41', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'fbfc049e-1393-4320-ad5d-2c1f7a1733f9'	System	08 Dec 2020 22:42:51
User entered 'No (N)'	System	08 Dec 2020 22:42:51

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-12-08T17:42:45', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'fbfc049e-1393-4320-ad5d-2c1f7a1733f9' User entered '08 Dec 2020 17:42:45'	System	08 Dec 2020 22:42:51
	System	08 Dec 2020 22:42:51

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-12-15T08:32:51', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'e889e361-70ab-439e-b52a-27739d87896b' User entered 'No (N)'	System	15 Dec 2020 13:33:16
	System	15 Dec 2020 13:33:16

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-12-15T08:33:01', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'e889e361-70ab-439e-b52a-27739d87896b' User entered 'No (N)'	System	15 Dec 2020 13:33:16
	System	15 Dec 2020 13:33:16

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-12-15T08:33:13', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'e889e361-70ab-439e-b52a-27739d87896b' User entered '15 Dec 2020 08:33:13'	System	15 Dec 2020 13:33:16
	System	15 Dec 2020 13:33:16

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-12-21T14:34:28', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '18c193b5-67cc-45d1-a0a5-757ba042d09e' User entered 'No (N)'	System	21 Dec 2020 19:34:42
	System	21 Dec 2020 19:34:42

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-12-21T14:34:33', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '18c193b5-67cc-45d1-a0a5-757ba042d09e' User entered 'No (N)'	System	21 Dec 2020 19:34:42
	System	21 Dec 2020 19:34:42

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-12-21T14:34:39', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '18c193b5-67cc-45d1-a0a5-757ba042d09e' User entered '21 Dec 2020 14:34:39'	System	21 Dec 2020 19:34:42
	System	21 Dec 2020 19:34:42

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-12-29T08:25:48', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'fdbe7ed6-ce40-4f09-9d11-1a2689fb416a' User entered 'No (N)'	System	29 Dec 2020 13:26:03
	System	29 Dec 2020 13:26:03

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-12-29T08:25:53', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'fdbe7ed6-ce40-4f09-9d11-1a2689fb416a' User entered 'No (N)'	System	29 Dec 2020 13:26:03
	System	29 Dec 2020 13:26:03

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2020-12-29T08:26:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'fdbe7ed6-ce40-4f09-9d11-1a2689fb416a' User entered '29 Dec 2020 08:26:00'	System	29 Dec 2020 13:26:03
	System	29 Dec 2020 13:26:03

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-01-04T22:10:54', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '7dd20ea3-8925-4bf5-bfbe-1dc7467c05e6'	System	05 Jan 2021 03:11:14
User entered 'No (N)'	System	05 Jan 2021 03:11:14

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-01-04T22:11:05', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '7dd20ea3-8925-4bf5-bfbe-1dc7467c05e6'	System	05 Jan 2021 03:11:14
User entered 'No (N)'	System	05 Jan 2021 03:11:14

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-01-04T22:11:09', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '7dd20ea3-8925-4bf5-bfbe-1dc7467c05e6' User entered '04 Jan 2021 22:11:09'	System	05 Jan 2021 03:11:14
	System	05 Jan 2021 03:11:14

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-01-11T09:21:53', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '3222fc3a-93b1-41f2-a0d1-3267dee08dd8' User entered 'No (N)'	System	11 Jan 2021 14:22:05
	System	11 Jan 2021 14:22:05

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-01-11T09:21:56', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '3222fc3a-93b1-41f2-a0d1-3267dee08dd8' User entered 'No (N)'	System	11 Jan 2021 14:22:05
	System	11 Jan 2021 14:22:05

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-01-11T09:22:01', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '3222fc3a-93b1-41f2-a0d1-3267dee08dd8' User entered '11 Jan 2021 09:22:01'	System	11 Jan 2021 14:22:05
	System	11 Jan 2021 14:22:05

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-01-18T22:09:27', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '313303b8-0478-42f9-a1fb-9679586418bc' User entered 'No (N)'	System	19 Jan 2021 03:09:50
	System	19 Jan 2021 03:09:50

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-01-18T22:09:40', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '313303b8-0478-42f9-a1fb-9679586418bc' User entered 'No (N)'	System	19 Jan 2021 03:09:50
	System	19 Jan 2021 03:09:50

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-01-18T22:09:47', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '313303b8-0478-42f9-a1fb-9679586418bc' User entered '18 Jan 2021 22:09:47'	System	19 Jan 2021 03:09:50
	System	19 Jan 2021 03:09:50

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-01-27T15:33:15', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '4a948fa4-3860-4b29-8e99-6d3fd420873a' User entered 'No (N)'	System	27 Jan 2021 20:33:32
	System	27 Jan 2021 20:33:32

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-01-27T15:33:20', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '4a948fa4-3860-4b29-8e99-6d3fd420873a' User entered 'No (N)'	System	27 Jan 2021 20:33:32

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-01-27T15:33:28', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '4a948fa4-3860-4b29-8e99-6d3fd420873a' User entered '27 Jan 2021 15:33:28'	System	27 Jan 2021 20:33:32
	System	27 Jan 2021 20:33:32

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-02-03T19:04:21', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '88e7dfc5-3c1b-43f9-acfd-2a9d05f732e4' User entered 'No (N)'	System	04 Feb 2021 00:05:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-02-03T19:04:25', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '88e7dfc5-3c1b-43f9-acfd-2a9d05f732e4' User entered 'No (N)'	System	04 Feb 2021 00:05:59
	System	04 Feb 2021 00:05:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-02-03T19:04:34', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '88e7dfc5-3c1b-43f9-acfd-2a9d05f732e4' User entered '03 Feb 2021 19:04:34'	System	04 Feb 2021 00:05:59
	System	04 Feb 2021 00:05:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-02-08T14:57:38', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '31b32f7b-fe75-4381-a308-0cd6102f646c' User entered 'No (N)'	System	08 Feb 2021 19:57:59
	System	08 Feb 2021 19:57:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-02-08T14:57:45', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '31b32f7b-fe75-4381-a308-0cd6102f646c' User entered 'No (N)'	System	08 Feb 2021 19:57:59
	System	08 Feb 2021 19:57:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-02-08T14:57:56', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '31b32f7b-fe75-4381-a308-0cd6102f646c' User entered '08 Feb 2021 14:57:56'	System	08 Feb 2021 19:57:59
	System	08 Feb 2021 19:57:59

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-02-17T08:22:08', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd6743f36-14b5-44cf-a511-97e5ea6d2a19' User entered 'No (N)'	System	17 Feb 2021 13:22:34
	System	17 Feb 2021 13:22:34

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-02-17T08:22:18', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd6743f36-14b5-44cf-a511-97e5ea6d2a19' User entered 'No (N)'	System	17 Feb 2021 13:22:34
	System	17 Feb 2021 13:22:34

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-02-17T08:22:31', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd6743f36-14b5-44cf-a511-97e5ea6d2a19' User entered '17 Feb 2021 08:22:31'	System	17 Feb 2021 13:22:34
	System	17 Feb 2021 13:22:34

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-02-22T21:22:50', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'a860e965-99d3-475a-9108-160e60fe9f99'	System	23 Feb 2021 02:30:02
User entered 'No (N)'	System	23 Feb 2021 02:30:02

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-02-22T21:22:53', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'a860e965-99d3-475a-9108-160e60fe9f99'	System	23 Feb 2021 02:30:02
User entered 'No (N)'	System	23 Feb 2021 02:30:02

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-02-22T21:22:57', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'a860e965-99d3-475a-9108-160e60fe9f99' User entered '22 Feb 2021 21:22:57'	System	23 Feb 2021 02:30:02
	System	23 Feb 2021 02:30:02

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-03-03T07:55:06-05:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8e069028-6f24-462c-9815-2384510f47ab'	System	03 Mar 2021 12:55:19
User entered 'No (N)'	System	03 Mar 2021 12:55:19

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-03-03T07:55:09-05:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8e069028-6f24-462c-9815-2384510f47ab'	System	03 Mar 2021 12:55:19
User entered 'No (N)'	System	03 Mar 2021 12:55:19

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-03-03T07:55:12-05:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '8e069028-6f24-462c-9815-2384510f47ab' User entered '03 Mar 2021 07:55:12'	System	03 Mar 2021 12:55:19
	System	03 Mar 2021 12:55:19

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-03-16T20:12:32-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '4e8f4921-887c-4c00-8fbd-298b9a9ad9a0'	System	17 Mar 2021 00:13:03
User entered 'No (N)'	System	17 Mar 2021 00:13:03

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-03-16T20:12:45-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '4e8f4921-887c-4c00-8fbd-298b9a9ad9a0'	System	17 Mar 2021 00:13:03
User entered 'No (N)'	System	17 Mar 2021 00:13:03

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-03-16T20:12:57-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '4e8f4921-887c-4c00-8fbd-298b9a9ad9a0' User entered '16 Mar 2021 20:12:57'	System	17 Mar 2021 00:13:03
	System	17 Mar 2021 00:13:03

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-03-23T18:02:58-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '16506a4a-2a25-4116-8f99-54d2ed72de18' User entered 'No (N)'	System	23 Mar 2021 22:08:44
	System	23 Mar 2021 22:08:44

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-03-23T18:03:09-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '16506a4a-2a25-4116-8f99-54d2ed72de18'	System	23 Mar 2021 22:08:44
User entered 'No (N)'	System	23 Mar 2021 22:08:44

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-03-23T18:03:16-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '16506a4a-2a25-4116-8f99-54d2ed72de18'	System	23 Mar 2021 22:08:44
User entered '23 Mar 2021 18:03:16'	System	23 Mar 2021 22:08:44

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-03-31T17:26:41-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '599323ba-4361-4b29-9075-3389f14d7d5d'	System	06 Apr 2021 14:40:40
User entered 'No (N)'	System	06 Apr 2021 14:40:40

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-03-31T17:26:53-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '599323ba-4361-4b29-9075-3389f14d7d5d'	System	06 Apr 2021 14:40:40
User entered 'No (N)'	System	06 Apr 2021 14:40:40

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-03-31T17:26:58-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '599323ba-4361-4b29-9075-3389f14d7d5d'	System	06 Apr 2021 14:40:40
User entered '31 Mar 2021 17:26:58'	System	06 Apr 2021 14:40:40

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-04-06T10:40:41-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '9519399d-2bb0-4334-a8ad-61bff58d91bc' User entered 'No (N)'	System	06 Apr 2021 14:40:53
	System	06 Apr 2021 14:40:53

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-04-06T10:40:44-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '9519399d-2bb0-4334-a8ad-61bff58d91bc'	System	06 Apr 2021 14:40:53
User entered 'No (N)'	System	06 Apr 2021 14:40:53

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-04-06T10:40:48-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '9519399d-2bb0-4334-a8ad-61bff58d91bc' User entered '06 Apr 2021 10:40:48'	System	06 Apr 2021 14:40:53
	System	06 Apr 2021 14:40:53

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-04-13T20:01:27-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd994dbe8-bb10-4076-9790-e439fd7ae497'	System	14 Apr 2021 00:01:40
User entered 'No (N)'	System	14 Apr 2021 00:01:40

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-04-13T20:01:31-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd994dbe8-bb10-4076-9790-e439fd7ae497'	System	14 Apr 2021 00:01:40
User entered 'No (N)'	System	14 Apr 2021 00:01:40

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-04-13T20:01:34-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'd994dbe8-bb10-4076-9790-e439fd7ae497'	System	14 Apr 2021 00:01:40
User entered '13 Apr 2021 20:01:34'	System	14 Apr 2021 00:01:40

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-04-21T07:00:21-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'c8e3adef-fd6d-47ea-bdfc-e83ec3760392'	System	21 Apr 2021 11:00:33
User entered 'No (N)'	System	21 Apr 2021 11:00:33

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-04-21T07:00:24-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'c8e3adef-fd6d-47ea-bdfc-e83ec3760392'	System	21 Apr 2021 11:00:33
User entered 'No (N)'	System	21 Apr 2021 11:00:33

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-04-21T07:00:29-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: 'c8e3adef-fd6d-47ea-bdfc-e83ec3760392'	System	21 Apr 2021 11:00:33
User entered '21 Apr 2021 07:00:29'	System	21 Apr 2021 11:00:33

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-05-03T22:50:41-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '970d1c60-03cd-43ae-80e8-4d194190446c'	System	04 May 2021 02:53:30
User entered 'No (N)'	System	04 May 2021 02:53:30

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

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 (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-05-03T22:50:55-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '970d1c60-03cd-43ae-80e8-4d194190446c'	System	04 May 2021 02:53:30
User entered 'No (N)'	System	04 May 2021 02:53:30

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-05-03T22:51:00-04:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '970d1c60-03cd-43ae-80e8-4d194190446c'	System	04 May 2021 02:53:30
User entered '03 May 2021 22:51:00'	System	04 May 2021 02:53:30

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 18:48:04

US3242231

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:11:06

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:48:04
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 18:48:04

US3242231

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:11:06

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-03-11T17:05:40-05:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '41f37c81-4ec6-45c2-a3ba-bf834cd7a891'	(b) (4), (b) (6)	11 Mar 2021 22:05:52
User entered 'No (N)'	System	11 Mar 2021 22:05:52

US3242231

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:11:06

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 07:41:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (619EE517-323B-4392-983E-22F02237A40E)', Time: '2021-03-11T17:05:50-05:00', User OID: 'PatientReportedOutcome (US3242231)', ODM File OID: '41f37c81-4ec6-45c2-a3ba-bf834cd7a891'	(b) (4), (b) (6)	11 Mar 2021 22:05:52
User entered '11 Mar 2021 17:05:50'	System	11 Mar 2021 22:05:52

US3242231

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	17 Nov 2020 17:38:27
	(b) (4)	

US3242231

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered '17 Nov 2020'	Erynn McKinley (b) (4)	17 Nov 2020 17:38:27
	(b) (4)	

US3242231

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	17 Nov 2020 17:38:27
	(b) (4)	

US3242231

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered empty.	Erynn McKinley (b) (4)	17 Nov 2020 17:38:27
	(b) (4)	

US3242231

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:12:28
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	17 Nov 2020 17:38:31
	(b) (4)	

US3242231

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:39:01
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 17:38:31
	System	

US3242231

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	23 Dec 2020 18:00:27
	(b) (4)	

US3242231

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered '22 Dec 2020'	Erynn McKinley (b) (4)	23 Dec 2020 18:00:27
	(b) (4)	

US3242231

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	23 Dec 2020 18:00:27
	(b) (4)	

US3242231

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered empty.	Erynn McKinley (b) (4)	23 Dec 2020 18:00:27
	(b) (4)	

US3242231

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	23 Dec 2020 18:00:31
	(b) (4)	

US3242231

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
User entered 'I'	(b) (4), (b) (6) System	23 Dec 2020 18:00:31

US3242231

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	20 Jan 2021 21:55:11
	(b) (4)	

US3242231

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered '20 Jan 2021'	Erynn McKinley (b) (4)	20 Jan 2021 21:55:11
	(b) (4)	

US3242231

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	20 Jan 2021 21:55:11
	(b) (4)	

US3242231

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered empty.	Erynn McKinley (b) (4)	20 Jan 2021 21:55:11
	(b) (4)	

US3242231

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	20 Jan 2021 21:55:14
	(b) (4)	

US3242231

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
User entered 'I'	(b) (4), (b) (6) System	20 Jan 2021 21:55:14

US3242231

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:05:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	22 Feb 2021 22:19:14
	(b) (4)	

US3242231

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:05:50
User entered '22 Feb 2021'	Erynn McKinley (b) (4)	22 Feb 2021 22:19:14
	(b) (4)	

US3242231

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:05:50
User entered 'Contact Made (CONTACT MADE)'	Erynn McKinley (b) (4)	22 Feb 2021 22:19:14
	(b) (4)	

US3242231

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:05:50
User entered empty.	Erynn McKinley (b) (4)	22 Feb 2021 22:19:14
	(b) (4)	

US3242231

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:05:50
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	22 Feb 2021 22:19:17
	(b) (4)	

US3242231

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
User entered 'I'	(b) (4), (b) (6) System	22 Feb 2021 22:19:17

US3242231

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:15:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	24 Mar 2021 17:00:03
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:15:22
User entered '24 Mar 2021'	Erynn McKinley (b) (4)	24 Mar 2021 17:00:03
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:15:22
User entered 'Clinic (Clinic)'	Erynn McKinley (b) (4)	24 Mar 2021 17:00:03
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
User entered 'VISIT4'	(b) (4), (b) (6) System	24 Mar 2021 17:00:03

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:57:12
User entered 'No (N)'	Erynn McKinley (b) (4)	30 Mar 2021 21:51:05
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:57:12
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:51:05
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:57:12
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:51:05
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:51:05

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:57:12
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:51:05
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:57:12
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:51:05
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:57:12
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:51:05
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:57:12
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:51:05
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:51:05

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:57:12
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:51:05
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:51:05

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:57:12
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:51:05
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:51:05

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	01 Apr 2021 19:57:12
User entered empty.	Erynn McKinley (b) (4)	30 Mar 2021 21:51:05
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 21:51:05

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 16:35:34

US3242231

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:11:06

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 16:35:34

US3242231

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:06

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:15:22
User entered 'No (N)'	Erynn McKinley (b) (4)	24 Mar 2021 17:00:09
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:11:06

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:15:22
User entered empty.	Erynn McKinley (b) (4)	24 Mar 2021 17:00:09
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:15:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	24 Mar 2021 17:00:19
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:15:22
User entered '24 Mar 2021'	Erynn McKinley (b) (4)	24 Mar 2021 17:00:19
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:15:22
User entered '12:05'	Erynn McKinley (b) (4)	24 Mar 2021 17:00:19
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
User entered '24 Mar 2021 12:05'	(b) (4), (b) (6) System	24 Mar 2021 17:00:19

US3242231

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	25 Mar 2021 18:15:22
User entered 'Yes (Y)'	Erynn McKinley (b) (4)	24 Mar 2021 17:00:24
	(b) (4)	

US3242231

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:35:34
User entered '1'	(b) (4), (b) (6) System	24 Mar 2021 17:00:24

US3242231

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	22 Apr 2021 16:37:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:13:47

US3242231

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	22 Apr 2021 16:37:29
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:13:47

US3242231

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	22 Apr 2021 16:37:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:13:47

US3242231

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:11:06

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	22 Apr 2021 16:37:29
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:13:47

US3242231

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	22 Apr 2021 16:37:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 12:13:07

US3242231

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:11:06

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 12:13:07

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Jan 2021 17:06:34

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered '19 Jan 2021'	Donna Toepfer (b) (4)	19 Jan 2021 17:06:34

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Clinic (Clinic)'	Donna Toepfer (b) (4)	19 Jan 2021 17:06:34

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:11:06

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	19 Jan 2021 17:06:34

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:06

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered '19 Jan 2021'	Donna Toepfer (b) (4)	19 Jan 2021 17:06:50

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:06

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:03:28

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:06

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Jan 2021 17:06:50

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:06

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User signature succeeded.	(b) (4), (b) (6) Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:03:28

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:06

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered '19 Jan 2021'	Donna Toepfer (b) (4)	19 Jan 2021 17:06:50

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:06

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'mRNA-1273 (mRNA-1273)'	Donna Toepfer (b) (4)	19 Jan 2021 17:06:50

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:06

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 03:28:46
User entered 'mRNA-1273 (mRNA-1273)'	Donna Toepfer (b) (4)	19 Jan 2021 17:06:50

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:06

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 03:28:46
User entered 'mRNA-1273 (mRNA-1273)'	Donna Toepfer (b) (4)	19 Jan 2021 17:06:50

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:06

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'No (N)'	Donna Toepfer (b) (4)	19 Jan 2021 17:06:50

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:06

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	19 Jan 2021 17:06:50

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:11:06

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:57:28
User entered empty.	(b) (4), (b) (6) System	19 Jan 2021 17:06:50

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:56:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Jan 2021 17:07:06

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:56:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered '19 Jan 2021'	Donna Toepfer (b) (4)	19 Jan 2021 17:07:06

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:56:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered '11:12'	Donna Toepfer (b) (4)	19 Jan 2021 17:07:06

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:11:06

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:56:34
User entered '19 Jan 2021 11:12'	(b) (4), (b) (6) System	19 Jan 2021 17:07:06

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:11:06

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:56:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	19 Jan 2021 17:07:17

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:11:06

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:56:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered '19 Jan 2021'	Donna Toepfer (b) (4)	19 Jan 2021 17:07:17

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:11:06

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:56:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User entered '10:43'	Donna Toepfer (b) (4)	19 Jan 2021 17:07:17

US3242231

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:11:06

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:56:34
User entered '19 Jan 2021 10:43'	(b) (4), (b) (6) System	19 Jan 2021 17:07:17

US3242231

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:11:06

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:33:24
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:51
DataPoint Un-verified.	(b) (4), (b) (6)	11 Sep 2020 17:41:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 17:41:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Sep 2020 18:55:19
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 14:33:49

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:46:59
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 15:50:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 15:50:59
	(b) (4)	
Data point term sent to Coder	System	15 Dec 2020 15:49:56
DataPoint Un-verified.	Donna Toepfer (b) (4)	15 Dec 2020 15:49:01
Coding entries removed.	Donna Toepfer (b) (4)	15 Dec 2020 15:49:01
User entered 'Worsening of Hyperlipidemia' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Dec 2020 15:49:01
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 18:57:44
	(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 18:57:44
	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 18:56:27
User entered 'Hypercholesterolemia'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '1 Sep 2020'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
User signature succeeded.	(b) (4), (b) (6) Jon Finley (b) (4)	20 Apr 2021 21:22:19
DataPoint Un-verified.	(b) (4) Donna Toepfer (b) (4)	20 Apr 2021 18:54:48
Signature has been broken.	Donna Toepfer (b) (4)	20 Apr 2021 18:54:48
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Apr 2021 18:54:48
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or returned to its baseline state and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 13:41:13
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or returned to its baseline state and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'still ongoing' (Site from DM).	Donna Toepfer (b) (4)	13 Jan 2021 17:26:24
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved or returned to its baseline state and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 14:03:46
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:19
	(b) (4)	
DataPoint Un-verified.	Donna Toepfer (b) (4)	20 Apr 2021 18:54:48
Signature has been broken.	Donna Toepfer (b) (4)	20 Apr 2021 18:54:48
User entered '08 Feb 2021' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Apr 2021 18:54:48
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
User entered empty.	(b) (4), (b) (6) System	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 01:20:34
User signature succeeded.	Nathan Segall (b) (4) [REDACTED]	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4) [REDACTED] [REDACTED]	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 18:58:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 18:58:22
User entered 'None (NONE)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	10 Sep 2020 18:58:22
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 18:56:16
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'I'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
User signature succeeded.	(b) (4), (b) (6)	
	Jon Finley (b) (4)	20 Apr 2021 21:22:19
	(b) (4)	
DataPoint Un-verified.	Donna Toepfer (b) (4)	20 Apr 2021 18:54:48
Signature has been broken.	Donna Toepfer (b) (4)	20 Apr 2021 18:54:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Donna Toepfer (b) (4)	20 Apr 2021 18:54:48
Data Entry Error		
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
User entered '0'	(b) (4), (b) (6) System	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 01:20:34
User entered '1'	(b) (4), (b) (6) System	10 Sep 2020 18:56:16

US3242231

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:11:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 01:20:34

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:02:04
User entered	System	12 Sep 2020 18:58:27
'USA-US067-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	12 Sep 2020 18:58:27

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User closed query 'PV Query: Can you please provide further clarification for the event of hypertension reported as uncontrolled ie was there any need for intravenous medications or other interventions to controlled the BP than indicated below. Did the patient returned to baseline ? ' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:34:03
Query 'PV Query: Can you please provide further clarification for the event of hypertension reported as uncontrolled ie was there any need for intravenous medications or other interventions to controlled the BP than indicated below. Did the patient returned to baseline ? ' answered with 'subjects medication was increased, has returned to baseline' (Site from Safety).	Donna Toepfer (b) (4)	21 Sep 2020 12:04:27
User opened query 'PV Query: Can you please provide further clarification for the event of hypertension reported as uncontrolled ie was there any need for intravenous medications or other interventions to controlled the BP than indicated below. Did the patient returned to baseline ? ' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:08:11
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Uncontrolled hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:57:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:57:45
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 18:57:20
User entered 'Uncontrolled Hypertension'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '8 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '09 Sep 2020'	Donna Toepfer (b) (4) (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Donna Toepfer (b) (4) (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'I'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
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 Sep 2020 15:34:15
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 'covid testing not done' (Site from Safety).	Donna Toepfer (b) (4)	21 Sep 2020 12:04:58
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)	18 Sep 2020 18:07:29
User entered '08 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
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 Sep 2020 15:34:21
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	21 Sep 2020 12:05:07
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)	18 Sep 2020 18:06:34
User entered '09 Sep 2020'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4) (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4) (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'None (NONE)'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'I'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User closed query 'PV Query: Please provide the results of the ECHO.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:34:42
User closed query 'PV Query: Per paper SAE aortic aneurysm and hypocholesteremia are listed in relevant medical history. Please add to the EDC as applicable. (medical history is considered prior to the start of study, if it is a new finding please assess whether it meets crieteria for separate AE/SAE reporting). ' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:34:39
User closed query 'PV Query: Per paper SAE, the subject's gender was captured as female, while in the EDC it is male. Please confirm which is correct. ' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 15:34:28
Query 'PV Query: Please provide the results of the ECHO.' answered with 'echo is normal' (Site from Safety).	Donna Toepfer (b) (4)	21 Sep 2020 12:07:24
Query 'PV Query: Per paper SAE aortic aneurysm and hypocholesteremia are listed in relevant medical history. Please add to the EDC as applicable. (medical history is considered prior to the start of study, if it is a new finding please assess whether it meets crieteria for separate AE/SAE reporting). ' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	21 Sep 2020 12:05:33
Query 'PV Query: Per paper SAE, the subject's gender was captured as female, while in the EDC it is male. Please confirm which is correct. ' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	21 Sep 2020 12:05:28
User opened query 'PV Query: Please provide the results of the ECHO.' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:11:44
User opened query 'PV Query: Per paper SAE aortic aneurysm and hypocholesteremia are listed in relevant medical history. Please add to the EDC as applicable. (medical history is considered prior to the start of study, if it is a new finding please assess whether it meets crieteria for separate AE/SAE reporting). ' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:10:04

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Per paper SAE, the subject's gender was captured as female, while in the EDC it is male. Please confirm which is correct. ' (Site from Safety).	(b) (4), (b) (6)	18 Sep 2020 18:09:17
User entered 'Subject went to cardiologist to follow up for yearly appointment to follow up on aortic aneurysm. Echo was done and bp was 177/86 during procedure and cardiologist felt the need t observe subject overnight.'	Donna Toepfer (b) (4)	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:11:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Sep 2020 18:56:37

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 22:35:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 22:35:20
Data point term sent to Coder	System	22 Oct 2020 22:34:38
User entered 'Coronary Artery Disease'	Donna Toepfer (b) (4) (b) (4) (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '15 Oct 2020'	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Yes (Y)'	Donna Toepfer (b) (4) (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Grade 3/Severe (Grade 3/Severe)'	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4) (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4) (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'None (NONE)'	Donna Toepfer (b) (4) (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

None

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'I'	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:11:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Oct 2020 22:34:19

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:46:59
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:25:10
Un-reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 17:25:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:17:15
User entered 'USA-US067-2020-mRNA-1273-P301000013'	System	18 Nov 2020 14:17:11
User entered 'New'	(b) (4), (b) (6)	18 Nov 2020 14:17:11

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User coded data point as SOC: Vascular disorders, HLT: Aneurysms and artery dissections, HLT: Aortic aneurysms and dissections, PT: Aortic aneurysm, LLT: Aortic aneurysm - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 22:42:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 22:42:23
Data point term sent to Coder	System	22 Oct 2020 22:36:41
User entered 'Worsening Aortic Aneurysm'	Donna Toepfer (b) (4) (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '08 Oct 2020'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:46:59
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 21:05:51
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:46:59
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 21:05:51
User entered '28 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:46:59
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4. ' (Site from Safety). Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6) Donna Toepfer (b) (4)	02 Dec 2020 14:35:15 01 Dec 2020 16:07:08
DataPoint Un-verified.	Donna Toepfer (b) (4)	01 Dec 2020 16:03:31
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Dec 2020 16:03:31
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 18:08:44
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Grade 3/Severe (Grade 3/Severe)'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:46:59
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 21:05:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'No (N)'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:46:59
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	17 Nov 2020 21:07:32
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	17 Nov 2020 21:07:32
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	17 Nov 2020 21:05:51
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 21:05:51
User entered '1' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:46:59
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 21:05:51
User entered '27 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:46:59
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 21:05:51
User entered '06 Nov 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:46:59
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 21:07:32
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 21:07:32
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'Not Related (NOT RELATED)'	Donna Toepfer (b) (4) (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:46:59
DataPoint Un-verified.	Donna Toepfer (b) (4)	01 Dec 2020 16:08:26
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	01 Dec 2020 16:08:26
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered 'None (NONE)'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

None

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:49:39
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User closed query 'Per CDM: Please verify if this pertains to numerous corresponding Con Meds for indication 'WORSENING AORTIC ANEURYSM' in the CM eCRF? If yes, Please review dates and update Other Action Taken as appropriate.' ' (Site from DM). Query 'Per CDM: Please verify if this pertains to numerous corresponding Con Meds for indication 'WORSENING AORTIC ANEURYSM' in the CM eCRF? If yes, Please review dates and update Other Action Taken as appropriate.' ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	04 Mar 2021 13:25:22
DataPoint Un-verified.	Donna Toepfer (b) (4)	04 Mar 2021 13:24:58
Signature has been broken.	Donna Toepfer (b) (4)	04 Mar 2021 13:24:58
User entered '1' reason for change: Data Entry Error	Donna Toepfer (b) (4)	04 Mar 2021 13:24:58
User opened query 'Per CDM: Please verify if this pertains to numerous corresponding Con Meds for indication 'WORSENING AORTIC ANEURYSM' in the CM eCRF? If yes, Please review dates and update Other Action Taken as appropriate.' ' (Site from DM). Query 'Per CDM: Please verify if this pertains to CM# 18 'ACETAMINOPHEN' (01-NOV-2020) for indication 'WORSENING AORTIC ANEURYSM' in the CM eCRF? If yes, Please review dates and update Other Action Taken as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:36:03
User opened query 'Per CDM: Please verify if this pertains to CM# 18 'ACETAMINOPHEN' (01-NOV-2020) for indication 'WORSENING AORTIC ANEURYSM' in the CM eCRF? If yes, Please review dates and update Other Action Taken as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:23:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered '0'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 17:24:40
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'not applicable' (Site from Safety).	Donna Toepfer (b) (4)	09 Dec 2020 17:12:09
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 16:59:46
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 15:12:07
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'CABG is listed on 28Oct2020' (Site from DM).	Donna Toepfer (b) (4)	23 Nov 2020 15:28:53
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 02:49:09
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered 'I'	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:46:59
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 21:05:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Donna Toepfer (b) (4)	17 Nov 2020 21:05:51
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 20:02:23
Query 'Data is required. Please complete.' answered with 'still ongoing, subject has procedure planned for 10/28/2020' (Site from System).	Donna Toepfer (b) (4)	26 Oct 2020 15:37:01
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 22:35:46
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:46:59
User closed query 'PV Query: #1. Please clarify the basal condition for which CABG was performed. Does it meet criteria of AE/SAE? ' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 17:24:57
Query 'PV Query: #1. Please clarify the basal condition for which CABG was performed. Does it meet criteria of AE/SAE? ' answered with 'condition was for worsening of the aortic aneurysm' (Site from Safety).	Donna Toepfer (b) (4)	09 Dec 2020 21:36:47
User opened query 'PV Query: #1. Please clarify the basal condition for which CABG was performed. Does it meet criteria of AE/SAE? ' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 17:40:36
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 14:35:28
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE? ' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 14:35:26
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 14:35:23
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)	02 Dec 2020 14:35:20
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'None at this time' (Site from Safety).	Donna Toepfer (b) (4)	01 Dec 2020 16:09:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE? ' answered with 'remained for post observation' (Site from Safety).	Donna Toepfer (b) (4)	01 Dec 2020 16:09:14
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' answered with 'updated' (Site from Safety).	Donna Toepfer (b) (4)	01 Dec 2020 16:08:58
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 'no COVID-19 testing done' (Site from Safety).	Donna Toepfer (b) (4)	01 Dec 2020 16:08:42
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 18:10:20
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE? ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 18:10:03
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 18:09:49
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)	25 Nov 2020 18:09:32
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Nov 2020 21:07:32
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	17 Nov 2020 21:07:32
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 21:07:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject states she was admitted to Piedmont Atlanta on 10/27/2020, had CABG done on 10/28/2020 and was released on 11/06/2020.' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 21:07:32
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Nov 2020 21:05:51
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:58
User entered empty.	Donna Toepfer (b) (4)	22 Oct 2020 22:35:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:05:51
User entered '0'	System	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Oct 2020 22:35:46

US3242231

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:11:06

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 21:07:32

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:11:06

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:33:24
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:24
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 19:26:21

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:54:02
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	27 Aug 2020 19:54:02
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	27 Aug 2020 19:27:08
User entered 'Amlodipine'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:05

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:05

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Hypertension'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '5'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:05

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'mg (mg)'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:05

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:27:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:27:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:05

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:27:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '1 Jan 2016'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:05

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
DataPoint Un-verified.	Erynn McKinley (b) (4)	14 Dec 2020 16:26:39
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	14 Dec 2020 16:26:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
DataPoint Un-verified.	Erynn McKinley (b) (4)	14 Dec 2020 16:26:39
	(b) (4)	
User entered '09 Sep 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	14 Dec 2020 16:26:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:27:05

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
User entered '1'	(b) (4), (b) (6) System	27 Aug 2020 19:27:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
User entered '1'	(b) (4), (b) (6) System	27 Aug 2020 19:27:05

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:50:39
User entered '804 (804)'	(b) (4), (b) (6) System	27 Aug 2020 19:27:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:54:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:54:03
Data point term sent to Coder	System	27 Aug 2020 19:28:11
User entered 'Aspirin'	Donna Toepfer (b) (4) (b) (4) (b) (4)	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Heart health'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '81'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'mg (mg)'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '1 Jan 2011'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 19:27:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 12:44:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 12:44:35
Data point term sent to Coder	System	27 Aug 2020 19:28:14
User entered 'Metoprolol Succinate extended release'	Donna Toepfer (b) (4) (b) (4)	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Hypertension'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '25'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'mg (mg)'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '1 Jan 2016'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 19:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:54:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:54:06
Data point term sent to Coder	System	27 Aug 2020 19:29:15
User entered 'Omeprazole'	Donna Toepfer (b) (4) (b) (4)	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Gastroesophageal reflux disease'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '40'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'mg (mg)'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 13:58:15
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'correct per source' (Site from DM).	Donna Toepfer (b) (4)	16 Sep 2020 13:54:12
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 13:07:23
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '01 Feb 2018'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 19:28:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
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.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:25:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:25:47
Data point term sent to Coder	System	28 Aug 2020 15:25:00
Coding entries removed.	Donna Toepfer (b) (4)	28 Aug 2020 15:24:32
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.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:54:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:54:12
Data point term sent to Coder	System	27 Aug 2020 19:31:20
User entered 'TYleNOL' reason for change: Data Entry Error	Donna Toepfer (b) (4)	27 Aug 2020 19:30:20
Data point term sent to Coder	System	27 Aug 2020 19:29:16
User entered 'Tyelnol'	Donna Toepfer (b) (4)	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Headaches, Occasional' reason for change: Data Entry Error	Donna Toepfer (b) (4)	28 Aug 2020 15:24:32
User entered 'Generalized Pain'	Donna Toepfer (b) (4)	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '500'	Donna Toepfer (b) (4)	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'mg (mg)'	Donna Toepfer (b) (4)	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'UN UNK 2018'	Donna Toepfer (b) (4)	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '0'	Donna Toepfer (b) (4)	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Donna Toepfer (b) (4)	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 19:29:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 21:58:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 21:58:20
Data point term sent to Coder Coding entries removed.	System Erynn McKinley (b) (4)	20 Jan 2021 21:57:47 20 Jan 2021 21:57:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:56:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 19:00:46
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 19:00:46
Data point term sent to Coder User entered 'Ezetimibe'	System Donna Toepfer (b) (4)	10 Sep 2020 18:59:35 10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
DataPoint Un-verified.	Erynn McKinley (b) (4)	20 Jan 2021 21:57:13
User entered 'HYPERLIPIDEMIA' reason for change: Data Entry Error	Erynn McKinley (b) (4)	20 Jan 2021 21:57:13
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Hypercholesterolemia'	Donna Toepfer (b) (4)	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '10'	Donna Toepfer (b) (4)	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'mg (mg)'	Donna Toepfer (b) (4)	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '1 Sep 2020'	Donna Toepfer (b) (4)	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '0'	Donna Toepfer (b) (4)	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:19
	(b) (4)	
DataPoint Un-verified.	Donna Toepfer (b) (4)	20 Apr 2021 18:55:23
Signature has been broken.	Donna Toepfer (b) (4)	20 Apr 2021 18:55:23
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Apr 2021 18:55:23
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
	(b) (4), (b) (6)	
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:19
	(b) (4)	
DataPoint Un-verified.	Donna Toepfer (b) (4)	20 Apr 2021 18:55:23
Signature has been broken.	Donna Toepfer (b) (4)	20 Apr 2021 18:55:23
User entered '08 Feb 2021' reason for change: Data Entry Error	Donna Toepfer (b) (4)	20 Apr 2021 18:55:23
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Donna Toepfer (b) (4)	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
User entered '1'	(b) (4), (b) (6) System	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
User entered '1'	(b) (4), (b) (6) System	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:51:00
User entered '804 (804)'	(b) (4), (b) (6) System	10 Sep 2020 18:59:28

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 13:53:48
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	16 Sep 2020 13:53:48
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 13:53:23
User entered 'Amlodipine'	Donna Toepfer (b) (4)	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Donna Toepfer (b) (4)	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Hypertension'	Donna Toepfer (b) (4)	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '10'	Donna Toepfer (b) (4)	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'mg (mg)'	Donna Toepfer (b) (4)	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '9 Sep 2020'	Donna Toepfer (b) (4)	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '0'	Donna Toepfer (b) (4)	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
DataPoint Un-verified.	Erynn McKinley (b) (4)	14 Dec 2020 16:40:41
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	14 Dec 2020 16:40:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
DataPoint Un-verified.	Erynn McKinley (b) (4)	14 Dec 2020 16:40:41
	(b) (4)	
User entered '06 Nov 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	14 Dec 2020 16:40:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Donna Toepfer (b) (4)	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
User entered '1'	(b) (4), (b) (6) System	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
User entered '1'	(b) (4), (b) (6) System	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:06
User entered '804 (804)'	(b) (4), (b) (6) System	16 Sep 2020 13:52:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: PRAZOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:53:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:53:48
Data point term sent to Coder	System	16 Sep 2020 13:53:24
User entered 'Prazosin'	Donna Toepfer (b) (4) (b) (4) (b) (4)	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Donna Toepfer (b) (4)	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Hypertension'	Donna Toepfer (b) (4) (b) (4)	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'I'	Donna Toepfer (b) (4)	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'mg (mg)'	Donna Toepfer (b) (4)	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '9 Sep 2020'	Donna Toepfer (b) (4) (b) (4)	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '0'	Donna Toepfer (b) (4)	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Donna Toepfer (b) (4)	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Donna Toepfer (b) (4)	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 13:53:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
User closed query 'According to hospital records, the subject received Acetaminophen tablets (650 mg) from 01NOV2020 until 04NOV2020. Please review these source records and update conmeds as required ? ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 15:00:56
Query 'According to hospital records, the subject received Acetaminophen tablets (650 mg) from 01NOV2020 until 04NOV2020. Please review these source records and update conmeds as required ? ' answered with 'updated per source documents' (Site from CRA).	Donna Toepfer (b) (4)	19 Feb 2021 14:26:24
User opened query 'According to hospital records, the subject received Acetaminophen tablets (650 mg) from 01NOV2020 until 04NOV2020. Please review these source records and update conmeds as required ? ' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 15:25:50
User closed query 'According to hospital records, the subject received Acetaminophen tablets (650 mg) from 01NOV2020 until 04NOV2020. Please review these source records and update conmeds as required' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 15:25:50
Query 'According to hospital records, the subject received Acetaminophen tablets (650 mg) from 01NOV2020 until 04NOV2020. Please review these source records and update conmeds as required' answered with 'Site is working on 80 pages of meds this subject received and will have them entered as soon as they can.' (Site from CRA).	Susan Jones (b) (4)	17 Feb 2021 23:37:17
User opened query 'According to hospital records, the subject received Acetaminophen tablets (650 mg) from 01NOV2020 until 04NOV2020. Please review these source records and update conmeds as required' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 16:03:14
User closed query 'According to hospital records, the subject received Acetaminophen tablets (650 mg) from 01NOV2020 until 04NOV2020. Please review these source records and update conmeds as required' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 16:03:14

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
Query 'According to hospital records, the subject received Acetaminophen tablets (650 mg) from 01NOV2020 until 04NOV2020. Please review these source records and update conmeds as required' answered with 'hospital meds not entered in edc' (Site from CRA).	Donna Toepfer (b) (4)	10 Feb 2021 15:43:40
User opened query 'According to hospital records, the subject received Acetaminophen tablets (650 mg) from 01NOV2020 until 04NOV2020. Please review these source records and update conmeds as required' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:15:13
User closed query 'According to hospital records, the subject received Acetaminophen tablets (650 mg) from 01NOV2020 until 04NOV2020. Please review these source records and update conmeds as required.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:14:50
Query 'According to hospital records, the subject received Acetaminophen tablets (650 mg) from 01NOV2020 until 04NOV2020. Please review these source records and update conmeds as required.' answered with 'hospital meds not entered' (Site from CRA).	Donna Toepfer (b) (4)	30 Jan 2021 16:32:20
User opened query 'According to hospital records, the subject received Acetaminophen tablets (650 mg) from 01NOV2020 until 04NOV2020. Please review these source records and update conmeds as required.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 17:39:48
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 12:30:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 12:30:58
Data point term sent to Coder	System	29 Sep 2020 12:30:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	29 Sep 2020 12:29:30
User entered 'Acetaminophen'	Grace Newville (b) (4)	29 Sep 2020 12:29:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Grace Newville (b) (4)	29 Sep 2020 12:29:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'INJECTION SITE PAIN, LEFT ARM'	Grace Newville (b) (4)	29 Sep 2020 12:29:49
reason for change: Data Entry Error	(b) (4)	
User entered 'Injection site pain, right arm'	Grace Newville (b) (4)	29 Sep 2020 12:29:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '650'	Grace Newville (b) (4)	29 Sep 2020 12:29:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'mg (mg)'	Grace Newville (b) (4)	29 Sep 2020 12:29:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Grace Newville (b) (4)	29 Sep 2020 12:29:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'once (ONCE)'	Grace Newville (b) (4)	29 Sep 2020 12:29:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Grace Newville (b) (4)	29 Sep 2020 12:29:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Oral (ORAL)'	Grace Newville (b) (4)	29 Sep 2020 12:29:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered empty.	Grace Newville (b) (4)	29 Sep 2020 12:29:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '25 Sep 2020'	Grace Newville (b) (4)	29 Sep 2020 12:29:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '0'	Grace Newville (b) (4)	29 Sep 2020 12:29:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'No (N)'	Grace Newville (b) (4)	29 Sep 2020 12:29:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered '25 Sep 2020'	Grace Newville (b) (4)	29 Sep 2020 12:29:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:32
User entered 'Yes (Y)'	Grace Newville (b) (4)	29 Sep 2020 12:29:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
User entered empty.	(b) (4), (b) (6) System	29 Sep 2020 12:29:20

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
User entered empty.	(b) (4), (b) (6) System	29 Sep 2020 12:29:20

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:27
User entered empty.	(b) (4), (b) (6) System	29 Sep 2020 12:29:20

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
	(b) (4), (b) (6)	
User closed query 'According to hospital records, the subject received acetaminophen suppository (650 mg) on 28OCT2020. Please refer to medical records and add as indicated in conmeds' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 15:26:27
Query 'According to hospital records, the subject received acetaminophen suppository (650 mg) on 28OCT2020. Please refer to medical records and add as indicated in conmeds' answered with 'Medical records state subject was not given acetaminophen suppository. It was not administered because subject was able to take PO. ' (Site from CRA).	Susan Jones (b) (4)	17 Feb 2021 23:35:38
	(b) (4)	
User opened query 'According to hospital records, the subject received acetaminophen suppository (650 mg) on 28OCT2020. Please refer to medical records and add as indicated in conmeds' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 16:05:45
User closed query 'According to hospital records, the subject received acetaminophen suppository (650 mg) on 28OCT2020. Please refer to medical records and add as indicated in conmeds' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 16:05:45
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
Query 'According to hospital records, the subject received acetaminophen suppository (650 mg) on 28OCT2020. Please refer to medical records and add as indicated in conmeds' answered with 'hospital meds not entered in edc' (Site from CRA).	Donna Toepfer (b) (4)	10 Feb 2021 15:44:08
User opened query 'According to hospital records, the subject received acetaminophen suppository (650 mg) on 28OCT2020. Please refer to medical records and add as indicated in conmeds' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:27:30
User closed query 'According to hospital records, the subject received acetaminophen suppository (650 mg) on 28OCT2020. Please refer to medical records and add as indicated in conmeds.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:27:30

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Jan 2021 16:35:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	System	30 Jan 2021 16:34:38
Coding entries removed.	Donna Toepfer (b) (4)	30 Jan 2021 16:33:47
Query 'According to hospital records, the subject received acetaminophen suppository (650 mg) on 28OCT2020. Please refer to medical records and add as indicated in conmeds.' answered with 'hospital meds not entered' (Site from CRA).	Donna Toepfer (b) (4)	30 Jan 2021 16:32:43
User opened query 'According to hospital records, the subject received acetaminophen suppository (650 mg) on 28OCT2020. Please refer to medical records and add as indicated in conmeds.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 17:31:54
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Nov 2020 21:09:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	System	17 Nov 2020 21:09:08
User entered 'Acetaminophen'	Donna Toepfer (b) (4)	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:09:03
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User closed query 'Per CDM: Per previous query response "UPDATED"; however, the correction/update is not obvious please provide location of update such as the log line/form/data field updated. Thank you' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 09:08:07
Query 'Per CDM: Per previous query response "UPDATED"; however, the correction/update is not obvious please provide location of update such as the log line/form/data field updated. Thank you' answered with 'Line #2 procedures' (Site from DM).	Donna Toepfer (b) (4)	01 Feb 2021 13:26:39
User opened query 'Per CDM: Per previous query response "UPDATED"; however, the correction/update is not obvious please provide location of update such as the log line/form/data field updated. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 12:17:22
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 12:17:22
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	30 Jan 2021 16:33:59
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Jan 2021 16:33:47
User entered 'PAIN, PROCEDURE Coronary artery bypass graft' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Jan 2021 16:33:47

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 02:20:45
	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Pain, procedure CABG'	Donna Toepfer (b) (4)	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '650'	Donna Toepfer (b) (4)	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'mg (mg)'	Donna Toepfer (b) (4)	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '06 Nov 2020'	Donna Toepfer (b) (4)	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
DataPoint Un-verified.	Erynn McKinley (b) (4)	17 Feb 2021 20:07:57
	(b) (4)	
Signature has been broken.	Erynn McKinley (b) (4)	17 Feb 2021 20:07:57
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	17 Feb 2021 20:07:57
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
DataPoint Un-verified.	Erynn McKinley (b) (4)	17 Feb 2021 20:07:57
	(b) (4)	
Signature has been broken.	Erynn McKinley (b) (4)	17 Feb 2021 20:07:57
	(b) (4)	
User entered '01 Dec 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	17 Feb 2021 20:07:57
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
User entered empty.	(b) (4), (b) (6) System	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
User entered empty.	(b) (4), (b) (6) System	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:42
User entered empty.	(b) (4), (b) (6) System	17 Nov 2020 21:08:58

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
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: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 07:17:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 07:17:00
	(b) (4)	
Data point term sent to Coder	System	17 Nov 2020 21:10:11
User entered 'Augmentin'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Prophylaxis for post surgery infection'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '875/125'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'mg (mg)'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'twice daily (BID)'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '06 Nov 2020'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '12 Nov 2020'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
User entered '2'	(b) (4), (b) (6) System	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
User entered '1'	(b) (4), (b) (6) System	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:51:52
User entered '804 (804)'	(b) (4), (b) (6) System	17 Nov 2020 21:10:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 21:11:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 21:11:50
Data point term sent to Coder	System	17 Nov 2020 21:11:13
User entered 'Atorvastatin'	Donna Toepfer (b) (4) (b) (4) (b) (4)	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Hypercholesterolemia'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '40'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'mg (mg)'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
DataPoint Un-verified.	Erynn McKinley (b) (4)	17 Feb 2021 20:08:41
Signature has been broken.	Erynn McKinley (b) (4)	17 Feb 2021 20:08:41
User entered '02 Nov 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	17 Feb 2021 20:08:41
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '06 Nov 2020'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 21:10:55

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 21:38:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 21:38:49
Data point term sent to Coder	System	22 Dec 2020 21:37:11
Coding entries removed.	Donna Toepfer (b) (4)	22 Dec 2020 21:36:55
User entered 'BACITRACIN 500g' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Dec 2020 21:36:55
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:17:01
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 Nov 2020 07:17:01
Data point term sent to Coder	System	17 Nov 2020 21:12:14
User entered 'Bacitracin'	Donna Toepfer (b) (4)	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Prophylaxis, wound infection post procedure'	Donna Toepfer (b) (4)	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. Dose = 1; Unit = Application). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 10:15:36
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. Dose = 1; Unit = Application). Review and amend as appropriate. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	22 Dec 2020 21:38:13
User entered '1' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Dec 2020 21:36:55
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. Dose = 1; Unit = Application). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 13:19:06
User entered '500'	Donna Toepfer (b) (4)	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Other (OTHER)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Dec 2020 21:36:55
User entered 'g (g)'	Donna Toepfer (b) (4)	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Application' reason for change: Data Entry Error	Donna Toepfer (b) (4)	22 Dec 2020 21:36:55
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'three times daily (TID)'	Donna Toepfer (b) (4)	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Topical (TOPICAL)'	Donna Toepfer (b) (4)	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '06 Nov 2020'	Donna Toepfer (b) (4)	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '15 Nov 2020'	Donna Toepfer (b) (4)	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User closed query 'Per CDM: "Was this medication taken for solicited event?" Is recorded as "YES" however Indication is not listed in the solicited events as per protocol. Please review and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 13:47:06
	(b) (4), (b) (6)	
Query 'Per CDM: "Was this medication taken for solicited event?" Is recorded as "YES" however Indication is not listed in the solicited events as per protocol. Please review and update accordingly, else clarify.' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	28 Nov 2020 16:37:51
User entered 'No (N)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	28 Nov 2020 16:37:46
User opened query 'Per CDM: "Was this medication taken for solicited event?" Is recorded as "YES" however Indication is not listed in the solicited events as per protocol. Please review and update accordingly, else clarify.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 14:31:29
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
User entered '3'	(b) (4), (b) (6) System	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
User entered '1'	(b) (4), (b) (6) System	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:16
User entered '804 (804)'	(b) (4), (b) (6) System	17 Nov 2020 21:12:02

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:21:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:21:02
Data point term sent to Coder	System	17 Nov 2020 21:13:15
User entered 'Clopidogrel'	Donna Toepfer (b) (4) (b) (4)	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Prophylaxis, Antiplatelet, post CABG procedure'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '75'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'mg (mg)'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
DataPoint Un-verified.	Erynn McKinley (b) (4)	17 Feb 2021 20:09:30
Signature has been broken.	Erynn McKinley (b) (4)	17 Feb 2021 20:09:30
User entered '30 Oct 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	17 Feb 2021 20:09:30
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '06 Nov 2020'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 21:13:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:25:03
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 Nov 2020 07:25:03
Data point term sent to Coder	System	17 Nov 2020 21:14:15
User entered 'Ferrous Sulfate'	Donna Toepfer (b) (4) (b) (4)	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Prophylaxis, Anemia, Post CABG procedure'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '325'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'mg (mg)'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
DataPoint Un-verified.	Erynn McKinley (b) (4)	17 Feb 2021 20:10:21
Signature has been broken.	Erynn McKinley (b) (4)	17 Feb 2021 20:10:21
User entered '30 Oct 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	17 Feb 2021 20:10:21
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '06 Nov 2020'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 21:13:54

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 21:15:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 21:15:51
Data point term sent to Coder	System	17 Nov 2020 21:15:16
User entered 'Losartan'	Donna Toepfer (b) (4) (b) (4)	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Hypertension'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '12.5'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'mg (mg)'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'once daily (QD)'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 10:16:43
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'added after hospitalization ' (Site from DM).	Donna Toepfer (b) (4)	22 Dec 2020 21:39:57
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 13:21:30
User entered '06 Nov 2020'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 21:14:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
	(b) (4), (b) (6)	
User closed query 'According to Hospital records, the subject was given acetaminophen IM (1000 mg) on 28OCT2020. Please review the hospital records and update conmeds as required' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 15:04:07
Query 'According to Hospital records, the subject was given acetaminophen IM (1000 mg) on 28OCT2020. Please review the hospital records and update conmeds as required' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	15 Mar 2021 15:03:07
User opened query 'According to Hospital records, the subject was given acetaminophen IM (1000 mg) on 28OCT2020. Please review the hospital records and update conmeds as required' (Site from CRA).	(b) (4), (b) (6)	15 Mar 2021 13:41:34
User closed query 'According to Hospital records, the subject was given acetaminophen IM (1000 mg) on 28OCT2020. Please review the hospital records and update conmeds as required. ' (Site from CRA).	(b) (4), (b) (6)	15 Mar 2021 13:41:34
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Feb 2021 15:41:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Feb 2021 15:41:28
Query 'According to Hospital records, the subject was given acetaminophen IM (1000 mg) on 28OCT2020. Please review the hospital records and update conmeds as required. ' answered with 'hospital meds not entered in edc' (Site from CRA).	Donna Toepfer (b) (4)	30 Jan 2021 16:34:52
Data point term sent to Coder	System	30 Jan 2021 16:34:38
Coding entries removed.	Donna Toepfer (b) (4)	30 Jan 2021 16:34:32
User opened query 'According to Hospital records, the subject was given acetaminophen IM (1000 mg) on 28OCT2020. Please review the hospital records and update conmeds as required. ' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 17:20:49

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 07:33:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 07:33:01
Data point term sent to Coder	System	17 Nov 2020 21:15:16
User entered 'Tramadol'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
User closed query 'Per CDM: Per previous query response "updated, related to procedure"; however, the correction/update is not obvious please provide location of update such as the log line/form/data field updated. Thank you' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 09:08:38
Query 'Per CDM: Per previous query response "updated, related to procedure"; however, the correction/update is not obvious please provide location of update such as the log line/form/data field updated. Thank you' answered with 'Line #2 procedures' (Site from DM).	Donna Toepfer (b) (4)	01 Feb 2021 13:27:02
User opened query 'Per CDM: Per previous query response "updated, related to procedure"; however, the correction/update is not obvious please provide location of update such as the log line/form/data field updated. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 12:19:56
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 12:19:56
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'updated, related to procedure' (Site from DM).	Donna Toepfer (b) (4)	30 Jan 2021 16:35:04
DataPoint Un-verified.	Donna Toepfer (b) (4)	30 Jan 2021 16:34:32
User entered 'PAIN, POST Coronary artery bypass graft PROCEDURE' reason for change: Data Entry Error	Donna Toepfer (b) (4)	30 Jan 2021 16:34:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 02:21:22
	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Pain, post CABG procedure'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '50'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'mg (mg)'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Oral (ORAL)'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '06 Nov 2020'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered '0'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
DataPoint Un-verified.	Erynn McKinley (b) (4)	17 Feb 2021 20:10:59
	(b) (4)	
Signature has been broken.	Erynn McKinley (b) (4)	17 Feb 2021 20:10:59
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	17 Feb 2021 20:10:59
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'Yes (Y)'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
DataPoint Un-verified.	Erynn McKinley (b) (4)	17 Feb 2021 20:10:59
	(b) (4)	
Signature has been broken.	Erynn McKinley (b) (4)	17 Feb 2021 20:10:59
	(b) (4)	
User entered '20 Nov 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	17 Feb 2021 20:10:59
	(b) (4)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:21
User entered 'No (N)'	Donna Toepfer (b) (4)	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
User entered empty.	(b) (4), (b) (6) System	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
User entered empty.	(b) (4), (b) (6) System	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:52:58
User entered empty.	(b) (4), (b) (6) System	17 Nov 2020 21:14:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 20:14:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 20:14:03
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:13:02
User entered 'Acetaminophen'	Erynn McKinley (b) (4)	17 Feb 2021 20:12:38
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:12:38
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:12:38
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:17:47
DataPoint Un-verified.	Donna Toepfer (b) (4)	03 Mar 2021 13:46:20
Signature has been broken.	Donna Toepfer (b) (4)	03 Mar 2021 13:46:12
User entered '650' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 Mar 2021 13:46:12
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 00:55:34
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '6509'	Erynn McKinley (b) (4)	17 Feb 2021 20:12:38

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	17 Feb 2021 20:12:38
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:12:38
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:12:38
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:12:38
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	17 Feb 2021 20:12:38
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:12:38
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:23:18
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'value is correct' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:46:30
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 00:55:32
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '01 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:12:38

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:12:38
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:12:38
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:12:38
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:12:38
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:12:38

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:12:38

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:08
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:12:38

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 20:15:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 20:15:11
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:14:02
User entered 'Acetaminophen'	Erynn McKinley (b) (4)	17 Feb 2021 20:13:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:13:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:13:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '975'	Erynn McKinley (b) (4)	17 Feb 2021 20:13:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	17 Feb 2021 20:13:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:13:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:13:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:13:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	17 Feb 2021 20:13:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:13:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:13:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:13:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:13:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '01 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:13:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:13:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:13:48

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:13:48

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:28
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:13:48

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: BLOOD AND RELATED PRODUCTS, ATC: BLOOD SUBSTITUTES AND PLASMA PROTEIN FRACTIONS, PRODUCT: ALBUMIN HUMAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 17:17:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 17:17:54
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:17:04
User entered 'Albumin Human'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening of Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Sliding Scale'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'g (g)'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:16:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:16:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:16:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '01 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:16:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:16:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:35
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:16:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
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.	Coder Import (b) (4) (b) (4)	18 Feb 2021 06:55:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 06:55:46
Data point term sent to Coder	System	17 Feb 2021 20:17:19
User entered 'Albuterol'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:16:56

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:56
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:24:14
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'these were all meds that were taken in the hospital that we were told to list, its not clear what all they were taken for, but all during the SAE' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:47:30
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 00:55:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:56
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '2.5'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:56
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:56
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:16:56
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:56
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:16:56
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:56
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:16:56
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '01 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:56
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:56
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:56
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:56
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:16:56
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:16:56

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:16:56

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:45
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:16:56

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: ANTIFIBRINOLYTICS, ATC: AMINO ACIDS, PRODUCT: AMINOCAPROIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 07:11:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 07:11:46
Data point term sent to Coder	System	17 Feb 2021 20:19:21
User entered 'Aminocaproic Acid'	Erynn McKinley (b) (4)	17 Feb 2021 20:18:21

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:18:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:18:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '10'	Erynn McKinley (b) (4)	17 Feb 2021 20:18:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'g (g)'	Erynn McKinley (b) (4)	17 Feb 2021 20:18:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:18:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:18:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:18:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:18:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:18:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:18:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:18:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:18:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:18:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:18:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:18:21

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:18:21

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:53:57
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:18:21

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: VARIOUS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, ATC: BLOOD TRANSFUSION, AUXILIARY PRODUCTS, PRODUCT: ANTICOAGULANT CITRATE DEXTROSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 18:12:53
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 18:12:53
Data point term sent to Coder	System	17 Feb 2021 20:20:22
User entered 'Anticoagulant Citrate Dextrose Solution A'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:19:59

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:19:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:19:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '500'	Erynn McKinley (b) (4)	17 Feb 2021 20:19:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL (mL)'	Erynn McKinley (b) (4)	17 Feb 2021 20:19:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:19:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:19:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:19:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:19:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:19:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:19:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:19:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:19:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:19:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:19:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:19:59

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:19:59

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:05
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:19:59

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 06:51:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 06:51:47
Data point term sent to Coder	System	17 Feb 2021 20:22:28
User entered 'Absorbic Acid'	Erynn McKinley (b) (4)	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '500'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 09:24:53
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'value is correct ' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:47:56
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 00:55:04
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 15:19:44
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:21:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 07:22:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 07:22:46
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:23:28
User entered 'Aspirin (Chewable)'	Erynn McKinley (b) (4)	17 Feb 2021 20:22:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:22:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:22:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '81'	Erynn McKinley (b) (4)	17 Feb 2021 20:22:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	17 Feb 2021 20:22:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:22:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:22:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:22:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	17 Feb 2021 20:22:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:22:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:25:48
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'value is correct' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:48:11
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 00:56:16
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:22:48

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:22:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:22:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:22:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:22:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:22:48

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:22:48

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:40
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:22:48

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 07:29:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 07:29:46
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:24:29
User entered 'Aspirin (EC)'	Erynn McKinley (b) (4)	17 Feb 2021 20:23:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:23:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:23:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '81'	Erynn McKinley (b) (4)	17 Feb 2021 20:23:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	17 Feb 2021 20:23:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:23:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	17 Feb 2021 20:23:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:23:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	17 Feb 2021 20:23:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:23:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:23:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:23:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:23:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:23:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:23:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:23:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:23:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:46
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:23:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
	(b) (4), (b) (6)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: BACITRACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 04:57:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 04:57:00
	(b) (4)	
Data point term sent to Coder	System	05 Mar 2021 15:40:38
Coding entries removed.	Donna Toepfer (b) (4)	05 Mar 2021 15:40:28
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 07:57:56
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 07:57:56
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:25:31
User entered 'Bacitracin Injection (Irrigation Chest)'	Erynn McKinley (b) (4)	17 Feb 2021 20:25:18
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:25:18
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:25:18
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.'	(b) (4), (b) (6)	04 Mar 2021 09:26:45
(Site from DM).		
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.'	Donna Toepfer (b) (4)	03 Mar 2021 13:48:47
' answered with 'correct per hospital records' (Site from DM).		
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.'	(b) (4), (b) (6)	03 Mar 2021 00:59:56
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '100,000'	Erynn McKinley (b) (4)	17 Feb 2021 20:25:18
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	17 Feb 2021 20:25:18
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Units'	Erynn McKinley (b) (4)	17 Feb 2021 20:25:18
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:25:18
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:25:18
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User closed query 'Per CDM: Please update 'Route of administration' as per your response" (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 09:30:42
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
Query 'Per CDM: Please update 'Route of administration' as per your response" answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	05 Mar 2021 15:40:36
DataPoint Un-verified.	Donna Toepfer (b) (4)	05 Mar 2021 15:40:28
Signature has been broken.	Donna Toepfer (b) (4)	05 Mar 2021 15:40:28
User entered 'Other (OTHER)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	05 Mar 2021 15:40:28
User opened query 'Per CDM: Please update 'Route of administration' as per your response" (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:07:39
User closed query 'Per CDM: indication is recorded as Bactitracin INJECTION (Irrigation Chest) however route is 'Topical? Please review/update accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:07:39
Query 'Per CDM: indication is recorded as Bactitracin INJECTION (Irrigation Chest) however route is 'Topical? Please review/update accordingly. Thank you' answered with 'Unknown/taken from hospital records' (Site from DM).	Donna Toepfer (b) (4)	04 Mar 2021 13:26:54
User opened query 'Per CDM: indication is recorded as Bactitracin INJECTION (Irrigation Chest) however route is 'Topical? Please review/update accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:31:57
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Topical (TOPICAL)'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:25:18

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	Donna Toepfer (b) (4)	05 Mar 2021 15:40:28
Signature has been broken.	Donna Toepfer (b) (4)	05 Mar 2021 15:40:28
User entered 'Injection' reason for change: Data Entry Error	Donna Toepfer (b) (4)	05 Mar 2021 15:40:28
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:25:18
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:25:18
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:25:18
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:25:18
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:25:18
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:25:18
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:25:18

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:25:18

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:54:55
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:25:18

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 07:37:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 07:37:46
Data point term sent to Coder	System	17 Feb 2021 20:27:33
User entered 'Bacitracin Ointment'	Erynn McKinley (b) (4)	17 Feb 2021 20:27:05

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:27:05
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:27:05
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User closed query 'Per CDM: Dose per administration should be "UNK" if data is Unknown per CCG's. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:08:24
Query 'Per CDM: Dose per administration should be "UNK" if data is Unknown per CCG's. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Donna Toepfer (b) (4)	04 Mar 2021 13:31:27
DataPoint Un-verified.	Donna Toepfer (b) (4)	04 Mar 2021 13:31:19
Signature has been broken.	Donna Toepfer (b) (4)	04 Mar 2021 13:31:19
User entered 'UNK' reason for change: Data Entry Error	Donna Toepfer (b) (4)	04 Mar 2021 13:31:19
User opened query 'Per CDM: Dose per administration should be "UNK" if data is Unknown per CCG's. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:29:11
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Unknown'	Erynn McKinley (b) (4)	17 Feb 2021 20:27:05

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	17 Feb 2021 20:27:05
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:32:43
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' answered with 'Unknown, this is per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:50:49
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:00:21
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Units/Gram'	Erynn McKinley (b) (4)	17 Feb 2021 20:27:05
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:27:05
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:27:05
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Topical (TOPICAL)'	Erynn McKinley (b) (4)	17 Feb 2021 20:27:05
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:27:05
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:27:44
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'value is correct' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:50:57
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:00:28
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '04 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:27:05
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:27:05
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:27:05
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Feb 2021'	Erynn McKinley (b) (4)	17 Feb 2021 20:27:05
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:27:05
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:27:05

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:27:05

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:01
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:27:05

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: BUMETANIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 07:39:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 07:39:46
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:28:33
User entered 'Bumetanide'	Erynn McKinley (b) (4)	17 Feb 2021 20:28:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:28:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:28:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0.5'	Erynn McKinley (b) (4)	17 Feb 2021 20:28:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	17 Feb 2021 20:28:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:28:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	17 Feb 2021 20:28:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:28:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:28:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:28:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:33:06
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'value is correct' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:51:22
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:00:41
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '01 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:28:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:28:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '01 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:28:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:28:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:10
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:28:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: BUMETANIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 07:39:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 07:39:46
Data point term sent to Coder	System	17 Feb 2021 20:29:34
User entered 'Bumetanide'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:29:00

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:29:00
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:29:00
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'I'	Erynn McKinley (b) (4)	17 Feb 2021 20:29:00
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	17 Feb 2021 20:29:00
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:29:00
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	17 Feb 2021 20:29:00
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:29:00
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:29:00
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:29:00
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:33:45
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'value is correct' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:51:48
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:01:05
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '31 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:29:00

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:29:00
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:29:00
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '31 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:29:00
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:29:00
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:29:00

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:29:00

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:21
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:29:00

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 07:47:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 07:47:47
Data point term sent to Coder	System	17 Feb 2021 20:30:34
User entered 'Bupivacaine'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:30:12

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:30:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:30:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '30'	Erynn McKinley (b) (4)	17 Feb 2021 20:30:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL (mL)'	Erynn McKinley (b) (4)	17 Feb 2021 20:30:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:30:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:30:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:30:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	17 Feb 2021 20:30:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:34:12
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:52:27
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:01:24
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Local Infiltration Chest'	Erynn McKinley (b) (4)	17 Feb 2021 20:30:12

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:30:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:30:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:30:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:30:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:30:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:30:12

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:30:12

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:33
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:30:12

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
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.	Coder Import (b) (4)	18 Feb 2021 22:13:56
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 22:13:56
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:31:35
User entered 'Calcium Chloride'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:03
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:03
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:03
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'I'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:03
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'g (g)'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:03
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:31:03
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:03
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:31:03
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:03
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:31:03
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:03
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:03
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:03
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:03
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:03
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:31:03

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:31:03

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:55:47
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:31:03

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
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: ELECTROLYTE SOLUTIONS [UMBRELLA TERM] - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	19 Mar 2021 07:53:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:53:53
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 12:36:01
User closed query 'DM-Coding: please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	18 Feb 2021 12:35:02
Query 'DM-Coding: please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'There are no active ingredients in "Brackets" in the medical records..' (Site from System).	Susan Jones (b) (4) (b) (4)	18 Feb 2021 12:35:02
User opened query 'DM-Coding: please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4) (b) (4)	18 Feb 2021 08:00:48
Data point term sent to Coder	System	17 Feb 2021 20:32:36
User entered 'Cardioplegic Solution'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:31:59

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '300'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL (mL)'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:31:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:31:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:31:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:31:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:31:59

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:31:59

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:00
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:31:59

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 07:57:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 07:57:57
Data point term sent to Coder	System	17 Feb 2021 20:33:36
User entered 'Cefazolin'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:33:25

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:33:25
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:33:25
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:36:56
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:52:40
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:05:18
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Sliding Scale'	Erynn McKinley (b) (4)	17 Feb 2021 20:33:25
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'g (g)'	Erynn McKinley (b) (4)	17 Feb 2021 20:33:25
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:33:25
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:36:58
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:52:45
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:05:21
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:33:25
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:33:25
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:33:25
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:33:25
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:33:25
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:33:25
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:33:25
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:33:25
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:33:25
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:33:25

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:33:25

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:12
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:33:25

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT, PRODUCT: CHLORHEXIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 22:22:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 22:22:57
Data point term sent to Coder	System	17 Feb 2021 20:35:37
User entered 'Chlorhexidine'	Erynn McKinley (b) (4)	17 Feb 2021 20:34:40

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 12:36:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 12:36:27
User entered 'No (N)' reason for change: Data Entry Error	Susan Jones (b) (4)	18 Feb 2021 12:36:27
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 20:34:40
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:34:40
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:34:40
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '15'	Erynn McKinley (b) (4)	17 Feb 2021 20:34:40
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL (mL)'	Erynn McKinley (b) (4)	17 Feb 2021 20:34:40
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:34:40
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:34:40
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:34:40
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	17 Feb 2021 20:34:40
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:34:40
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '27 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:34:40
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:34:40
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:34:40
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '31 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:34:40
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:34:40
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:34:40

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:34:40

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:31
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:34:40

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTISEPTICS AND DISINFECTANTS, ATC: ANTISEPTICS AND DISINFECTANTS, ATC: BIGUANIDES AND AMIDINES, PRODUCT: CHLORHEXIDINE GLUCONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 22:20:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 22:20:57
Data point term sent to Coder	System	17 Feb 2021 20:37:38
User entered 'Chlorexidine Gluconate 2%'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 20:37:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:37:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:37:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'I'	Erynn McKinley (b) (4)	17 Feb 2021 20:37:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	17 Feb 2021 20:37:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Application'	Erynn McKinley (b) (4)	17 Feb 2021 20:37:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:37:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:37:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Topical (TOPICAL)'	Erynn McKinley (b) (4)	17 Feb 2021 20:37:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:37:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '27 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:37:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:37:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:37:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:37:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:37:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:37:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:37:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:43
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:37:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 22:57:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 22:57:56
Data point term sent to Coder	System	17 Feb 2021 20:39:40
User entered 'Dexamethasone'	Erynn McKinley (b) (4)	17 Feb 2021 20:39:09

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:39:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:39:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '4'	Erynn McKinley (b) (4)	17 Feb 2021 20:39:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	17 Feb 2021 20:39:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:39:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	17 Feb 2021 20:39:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:39:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:39:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:39:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:37:22
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'value is correct' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:53:10
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:05:41
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '30 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:39:09

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:39:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:39:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '30 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:39:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:39:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:39:09

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:39:09

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:56:55
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:39:09

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DEXMEDETOMIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 23:35:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 23:35:12
Data point term sent to Coder	System	17 Feb 2021 20:40:41
User entered 'Dexmedetomidine in Dextrose'	Erynn McKinley (b) (4)	17 Feb 2021 20:40:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:40:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:40:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Sliding Scale'	Erynn McKinley (b) (4)	17 Feb 2021 20:40:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	17 Feb 2021 20:40:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Mcg/kg/hr'	Erynn McKinley (b) (4)	17 Feb 2021 20:40:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:40:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:40:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:40:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:40:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:40:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:40:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:40:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:40:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:40:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:40:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:40:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:17
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:40:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 23:35:57
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 23:35:57
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:41:42
User entered 'Dextrose'	Erynn McKinley (b) (4)	17 Feb 2021 20:41:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:41:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:41:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '15'	Erynn McKinley (b) (4)	17 Feb 2021 20:41:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'g (g)'	Erynn McKinley (b) (4)	17 Feb 2021 20:41:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:41:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:41:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:41:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:41:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:41:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 09:37:45
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'value is correct' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:53:34
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:05:57
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:41:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:41:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:41:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:41:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:41:36
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:41:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:41:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:31
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:41:36

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 23:35:57
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 23:35:57
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:42:44
User entered 'Dextrose'	Erynn McKinley (b) (4)	17 Feb 2021 20:42:33
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:42:33
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:42:33
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Sliding Scale'	Erynn McKinley (b) (4)	17 Feb 2021 20:42:33
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	17 Feb 2021 20:42:33
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL/hr'	Erynn McKinley (b) (4)	17 Feb 2021 20:42:33
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:42:33
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:42:33
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:42:33
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:42:33
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:42:33
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:42:33
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:42:33
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:42:33
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:42:33
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:42:33

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:42:33

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:43
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:42:33

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 00:49:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 00:49:02
Data point term sent to Coder	System	17 Feb 2021 20:43:47
User entered 'Docusate Sodium'	Erynn McKinley (b) (4)	17 Feb 2021 20:43:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:43:32
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:20:58
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'value is correct' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:54:04
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:06:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:43:32
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '100'	Erynn McKinley (b) (4)	17 Feb 2021 20:43:32
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	17 Feb 2021 20:43:32
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:43:32
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:43:32
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:43:32
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	17 Feb 2021 20:43:32
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:43:32
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:43:32
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:43:32
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:43:32
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:43:32
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:43:32
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:43:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:43:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:57:55
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:43:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
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: ELECTROLYTES NOS, PRODUCTSYNONYM: ELECTROLYTE SOLUTIONS [ELECTROLYTES NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 00:55:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 00:55:00
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:47:50
User entered 'Electrolyte-R (pH7.4)'	Erynn McKinley (b) (4)	17 Feb 2021 20:47:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:47:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:47:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '2000'	Erynn McKinley (b) (4)	17 Feb 2021 20:47:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL (mL)'	Erynn McKinley (b) (4)	17 Feb 2021 20:47:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:47:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:47:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:47:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:47:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:47:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:47:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:47:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:47:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:47:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:47:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:47:11

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:47:11

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:08
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:47:11

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPINEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 01:02:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 01:02:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: EPINEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 00:57:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 00:57:59
Data point term sent to Coder	System	17 Feb 2021 20:48:51
User entered 'Epinephrine'	Erynn McKinley (b) (4)	17 Feb 2021 20:48:11

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:48:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:48:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Sliding Scale'	Erynn McKinley (b) (4)	17 Feb 2021 20:48:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	17 Feb 2021 20:48:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL/hr'	Erynn McKinley (b) (4)	17 Feb 2021 20:48:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:48:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:48:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:48:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:48:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:48:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:48:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:48:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '01 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:48:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:48:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:48:11

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:48:11

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:25
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:48:11

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 00:04:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 00:04:59
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:49:51
User entered 'Esomeprazole'	Erynn McKinley (b) (4)	17 Feb 2021 20:49:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:49:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 10:21:28
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:54:18
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:06:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:49:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '40'	Erynn McKinley (b) (4)	17 Feb 2021 20:49:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	17 Feb 2021 20:49:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:49:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:49:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:49:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	17 Feb 2021 20:49:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:49:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:49:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:49:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:49:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:49:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:49:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:49:07

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:49:07

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:35
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:49:07

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 01:04:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 01:04:00
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:52:52
User entered 'Ezetimibe'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:09:29
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:54:57
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:10:40
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '10'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:52:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:09:34
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:57:08
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:10:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:52:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:52:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:52:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:52:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:46
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:52:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 08:15:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 08:15:48
Data point term sent to Coder	System	17 Feb 2021 20:53:53
User entered 'Fentanyl'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '100'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	Donna Toepfer (b) (4)	03 Mar 2021 13:55:21
Signature has been broken.	Donna Toepfer (b) (4)	03 Mar 2021 13:55:21
User entered 'ug (ug)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 Mar 2021 13:55:21
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User closed query 'Per DM CLR: Please review and verify if the UNIT can be appropriately recorded as ug as it is one of the pre-listed options under UNIT. If yes, please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:10:00
Query 'Per DM CLR: Please review and verify if the UNIT can be appropriately recorded as ug as it is one of the pre-listed options under UNIT. If yes, please update accordingly. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:55:29
DataPoint Un-verified.	Donna Toepfer (b) (4)	03 Mar 2021 13:55:21
Signature has been broken.	Donna Toepfer (b) (4)	03 Mar 2021 13:55:21
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	03 Mar 2021 13:55:21
User opened query 'Per DM CLR: Please review and verify if the UNIT can be appropriately recorded as ug as it is one of the pre-listed options under UNIT. If yes, please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:11:00
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mcg'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:52:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:52:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:52:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:52:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:52:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:58:55
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:52:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 08:15:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 08:15:48
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:54:54
User entered 'Fentanyl'	Erynn McKinley (b) (4)	17 Feb 2021 20:54:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:54:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:54:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '50'	Erynn McKinley (b) (4)	17 Feb 2021 20:54:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	Donna Toepfer (b) (4)	03 Mar 2021 13:55:49
Signature has been broken.	Donna Toepfer (b) (4)	03 Mar 2021 13:55:49
User entered 'ug (ug)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 Mar 2021 13:55:49
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	17 Feb 2021 20:54:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User closed query 'Per DM CLR: Please review and verify if the UNIT can be appropriately recorded as ug as it is one of the pre-listed options under UNIT. If yes, please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:10:34
Query 'Per DM CLR: Please review and verify if the UNIT can be appropriately recorded as ug as it is one of the pre-listed options under UNIT. If yes, please update accordingly. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:55:55
DataPoint Un-verified.	Donna Toepfer (b) (4)	03 Mar 2021 13:55:49
Signature has been broken.	Donna Toepfer (b) (4)	03 Mar 2021 13:55:49
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	03 Mar 2021 13:55:49
User opened query 'Per DM CLR: Please review and verify if the UNIT can be appropriately recorded as ug as it is one of the pre-listed options under UNIT. If yes, please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:11:18
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mcg'	Erynn McKinley (b) (4)	17 Feb 2021 20:54:41

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:54:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:54:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:54:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:54:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:54:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:54:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:54:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:54:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:54:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:54:41

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:54:41

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:03
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:54:41

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 08:19:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 08:19:53
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:55:54
User entered 'Furosemide'	Erynn McKinley (b) (4)	17 Feb 2021 20:55:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:55:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:55:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '40'	Erynn McKinley (b) (4)	17 Feb 2021 20:55:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	17 Feb 2021 20:55:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:55:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:55:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:55:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:55:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:55:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:11:14
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'value is correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:56:09
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:11:39
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '30 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:55:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:55:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:55:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:55:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:55:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:55:42

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:55:42

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:11
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:55:42

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 08:44:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 08:44:48
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 20:57:25
User entered 'Heparin'	Erynn McKinley (b) (4)	17 Feb 2021 20:57:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:57:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 20:57:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Sliding Scale'	Erynn McKinley (b) (4)	17 Feb 2021 20:57:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	17 Feb 2021 20:57:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'units/mL'	Erynn McKinley (b) (4)	17 Feb 2021 20:57:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 20:57:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:57:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 20:57:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 20:57:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '27 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:57:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 20:57:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:57:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 20:57:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 20:57:09
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:57:09

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:57:09

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:18
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 20:57:09

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 08:43:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Feb 2021 08:43:49
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 21:00:33
User entered 'Hydralazine'	Erynn McKinley (b) (4)	17 Feb 2021 21:00:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:00:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 21:00:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '10'	Erynn McKinley (b) (4)	17 Feb 2021 21:00:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	17 Feb 2021 21:00:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:00:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 21:00:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:00:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 21:00:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:00:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:11:33
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:56:26
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:11:54
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '01 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 21:00:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 21:00:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:00:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 21:00:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:00:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:00:07

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:00:07

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 16:59:30
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:00:07

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
	(b) (4), (b) (6)	
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: GLUCOCORTICOIDS, PRODUCT: HYDROCORTISONE SODIUM SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 12:20:22
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 12:20:22
	(b) (4)	
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: GLUCOCORTICOIDS, PRODUCT: HYDROCORTISONE SODIUM SUCCINATE, PRODUCTSYNONYM: HYDROCORTISONE [HYDROCORTISONE SODIUM SUCCINATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Mar 2021 21:36:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Mar 2021 21:36:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	17 Feb 2021 21:01:33
User entered 'Hydrocortisone Sod Succinate'	Erynn McKinley (b) (4)	17 Feb 2021 21:01:01
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '100'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 11:12:26
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:56:40
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 01:12:07
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '31 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '31 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:54:28
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:01:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 08:42:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 08:42:59
Data point term sent to Coder	System	17 Feb 2021 21:02:35
User entered 'Hydromorphone'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:02:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:02:01
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 21:02:01
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0.5'	Erynn McKinley (b) (4)	17 Feb 2021 21:02:01
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	17 Feb 2021 21:02:01
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:02:01
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 21:02:01
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:02:01
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 21:02:01
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:02:01
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 21:02:01
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 21:02:01
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:02:01
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '04 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 21:02:01
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:02:01
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:02:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:02:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:01:59
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:02:01

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 08:19:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 08:19:53
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 21:03:38
User entered 'Insulin Detemir'	Erynn McKinley (b) (4)	17 Feb 2021 21:03:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:03:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:13:02
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:57:26
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:23:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 21:03:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Sliding Scale'	Erynn McKinley (b) (4)	17 Feb 2021 21:03:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	17 Feb 2021 21:03:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Units'	Erynn McKinley (b) (4)	17 Feb 2021 21:03:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 21:03:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:03:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Subcutaneous (SUBCUTANEOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 21:03:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:03:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '30 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 21:03:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 21:03:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:03:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '02 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 21:03:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:03:07
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:03:07

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:03:07

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:03:54
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:03:07

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 08:21:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 08:21:46
Data point term sent to Coder	System	17 Feb 2021 21:04:40
User entered 'Insulin Lispro'	Erynn McKinley (b) (4)	17 Feb 2021 21:04:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:04:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:13:27
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:57:40
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:24:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 21:04:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Sliding Scale'	Erynn McKinley (b) (4)	17 Feb 2021 21:04:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	17 Feb 2021 21:04:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Units'	Erynn McKinley (b) (4)	17 Feb 2021 21:04:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 21:04:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:04:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Subcutaneous (SUBCUTANEOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 21:04:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:04:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '30 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 21:04:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 21:04:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:04:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '03 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 21:04:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:04:22
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:04:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:04:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:10
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:04:22

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 08:21:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 08:21:45
Data point term sent to Coder	System	17 Feb 2021 21:05:40
User entered 'Insulin Regular'	Erynn McKinley (b) (4)	17 Feb 2021 21:05:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:05:24
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:16:40
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:57:49
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:24:26
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 21:05:24
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Sliding Scale'	Erynn McKinley (b) (4)	17 Feb 2021 21:05:24
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	17 Feb 2021 21:05:24
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL/hr'	Erynn McKinley (b) (4)	17 Feb 2021 21:05:24
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 21:05:24
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:05:24
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 21:05:24
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:05:24
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 21:05:24
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 21:05:24
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:05:24
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '31 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 21:05:24
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:05:24
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:05:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:05:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:17
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:05:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 21:09:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Feb 2021 21:09:04
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 21:07:42
User entered 'Lactated Ringers'	Erynn McKinley (b) (4)	17 Feb 2021 21:06:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:06:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 21:06:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Sliding Scale'	Erynn McKinley (b) (4)	17 Feb 2021 21:06:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	17 Feb 2021 21:06:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL/hr'	Erynn McKinley (b) (4)	17 Feb 2021 21:06:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 21:06:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:06:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	17 Feb 2021 21:06:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:06:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 21:06:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 21:06:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:06:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '31 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 21:06:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:06:48
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:06:48

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:06:48

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:34
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:06:48

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	05 Mar 2021 05:17:46
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 05:17:46
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	17 Feb 2021 21:08:43
User entered 'Lidocaine Patch 4%'	Erynn McKinley (b) (4) (b) (4)	17 Feb 2021 21:08:17

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:08:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	17 Feb 2021 21:08:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'I'	Erynn McKinley (b) (4)	17 Feb 2021 21:08:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	17 Feb 2021 21:08:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Application'	Erynn McKinley (b) (4)	17 Feb 2021 21:08:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	17 Feb 2021 21:08:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:08:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:17:44
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:58:08
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:24:58
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Topical (TOPICAL)'	Erynn McKinley (b) (4)	17 Feb 2021 21:08:17

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	17 Feb 2021 21:08:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	17 Feb 2021 21:08:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	17 Feb 2021 21:08:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:08:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	17 Feb 2021 21:08:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	17 Feb 2021 21:08:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:08:17

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:08:17

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:42
User entered empty.	(b) (4), (b) (6) System	17 Feb 2021 21:08:17

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 14:14:47
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 14:14:47
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder User entered 'Losartan'	System Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:48:50 18 Feb 2021 14:48:30

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:48:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 14:48:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '25'	Erynn McKinley (b) (4)	18 Feb 2021 14:48:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	18 Feb 2021 14:48:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:48:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	18 Feb 2021 14:48:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:48:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	18 Feb 2021 14:48:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:48:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:18:13
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:58:17
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:25:21
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '03 Nov 2020'	Erynn McKinley (b) (4)	18 Feb 2021 14:48:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 14:48:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:48:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	18 Feb 2021 14:48:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:48:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:48:30

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:48:30

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:02:52
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:48:30

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
	(b) (4), (b) (6)	
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Apr 2021 07:18:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Apr 2021 07:18:48
	(b) (4)	
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 10:12:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Mar 2021 10:12:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 14:50:56
User entered 'Magnesium Sulfate in Sodium Chloride'	Erynn McKinley (b) (4)	18 Feb 2021 14:49:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '100'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL/hr'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 09:41:02
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:58:32
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 01:25:46
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '31 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '31 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:53:01
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:49:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
	(b) (4), (b) (6)	
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 07:18:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 07:18:48
	(b) (4)	
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 10:14:03
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 10:14:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 14:51:57
User entered 'Magnesium Sulfate in water'	Erynn McKinley (b) (4)	18 Feb 2021 14:51:23
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '2/50'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'g/mL/hr'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:34
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:51:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
	(b) (4), (b) (6)	
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 07:18:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 07:18:48
	(b) (4)	
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: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 10:14:04
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 10:14:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 14:52:57
User entered 'Magnesium Sulfate in water'	Erynn McKinley (b) (4)	18 Feb 2021 14:52:29
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '4/50'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'g/mL/hr'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'once (ONCE)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 09:40:44
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:58:48
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 01:30:36
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '01 Nov 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '01 Nov 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:00:39
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:52:29

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
	(b) (4), (b) (6)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, PRODUCT: MANNITOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:27:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:27:47
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 14:54:00
User entered 'Mannitol'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:53:20

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:53:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 14:53:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '25'	Erynn McKinley (b) (4)	18 Feb 2021 14:53:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'g (g)'	Erynn McKinley (b) (4)	18 Feb 2021 14:53:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:53:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	18 Feb 2021 14:53:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:53:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	18 Feb 2021 14:53:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:53:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 14:53:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 14:53:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:53:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 14:53:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:53:20
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:53:20

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:53:20

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:04:45
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:53:20

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 14:24:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 14:24:48
User signature succeeded.	Nathan Segall (b) (4) [REDACTED] [REDACTED]	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 14:55:01
User entered 'Melatonin'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:54:13

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:54:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 14:54:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '3'	Erynn McKinley (b) (4)	18 Feb 2021 14:54:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	18 Feb 2021 14:54:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:54:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	18 Feb 2021 14:54:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:54:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	18 Feb 2021 14:54:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:54:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:40:23
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:59:00
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:31:04
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '03 Nov 2020'	Erynn McKinley (b) (4)	18 Feb 2021 14:54:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 14:54:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:54:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	18 Feb 2021 14:54:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:54:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:54:13

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:54:13

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:00
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:54:13

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	08 Mar 2021 07:36:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:36:01
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder User entered 'Metoprolol Tartate'	System Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:56:01 18 Feb 2021 14:55:21

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:55:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 14:55:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '25'	Erynn McKinley (b) (4)	18 Feb 2021 14:55:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	18 Feb 2021 14:55:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:55:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	18 Feb 2021 14:55:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:55:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	18 Feb 2021 14:55:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:55:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '27 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 14:55:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 14:55:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:55:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 14:55:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:55:21
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:55:21

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:55:21

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (64)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:07
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:55:21

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
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), (b) (6) Coder Import (b) (4) (b) (4)	17 Mar 2021 10:26:41
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 10:26:41
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder User entered 'Medodrine'	System Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:57:04 18 Feb 2021 14:56:11

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:56:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 14:56:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '5'	Erynn McKinley (b) (4)	18 Feb 2021 14:56:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	18 Feb 2021 14:56:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:56:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	18 Feb 2021 14:56:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:56:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	18 Feb 2021 14:56:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:56:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:39:55
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:59:17
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:30:50
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '31 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 14:56:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 14:56:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:56:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '01 Nov 2020'	Erynn McKinley (b) (4)	18 Feb 2021 14:56:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:56:11
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:56:11

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:56:11

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (65)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:16
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:56:11

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: PHOSPHODIESTERASE INHIBITORS, PRODUCT: MILRINONE - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	08 Mar 2021 07:40:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:40:10
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder User entered 'Milrinone'	System Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:58:06 18 Feb 2021 14:57:17

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:57:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 14:57:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Sliding Scale'	Erynn McKinley (b) (4)	18 Feb 2021 14:57:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	18 Feb 2021 14:57:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL/hr'	Erynn McKinley (b) (4)	18 Feb 2021 14:57:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	18 Feb 2021 14:57:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:57:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	18 Feb 2021 14:57:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:57:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 14:57:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 14:57:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:57:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '01 Nov 2020'	Erynn McKinley (b) (4)	18 Feb 2021 14:57:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:57:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:57:17

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:57:17

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (66)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:27
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:57:17

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: MUPIROCIN - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	17 Mar 2021 14:32:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 14:32:51
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 15:00:08
User entered 'Mupirocin 2%'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 14:59:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:59:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:39:14
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:59:45
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:31:44
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 14:59:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'I'	Erynn McKinley (b) (4)	18 Feb 2021 14:59:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	18 Feb 2021 14:59:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Application'	Erynn McKinley (b) (4)	18 Feb 2021 14:59:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	18 Feb 2021 14:59:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:59:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:39:17
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 13:59:55
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:31:46
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Nasal (NASAL)'	Erynn McKinley (b) (4)	18 Feb 2021 14:59:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 14:59:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '27 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 14:59:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 14:59:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:59:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 14:59:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 14:59:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:59:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:59:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (67)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:35
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 14:59:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: NOREPINEPHRINE BITARTRATE - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	18 Mar 2021 10:23:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 10:23:35
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder User entered 'Norepinephrine Bitartrate'	System Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 15:02:11 18 Feb 2021 15:01:17

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:01:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 15:01:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Sliding Scale'	Erynn McKinley (b) (4)	18 Feb 2021 15:01:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	18 Feb 2021 15:01:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL/hr'	Erynn McKinley (b) (4)	18 Feb 2021 15:01:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	18 Feb 2021 15:01:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:01:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	18 Feb 2021 15:01:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:01:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 15:01:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 15:01:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:01:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 15:01:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:01:17
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:01:17

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:01:17

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (68)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:43
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:01:17

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
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)	19 Feb 2021 10:55:01
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Feb 2021 10:55:01
	(b) (4)	
Data point term sent to Coder	System	18 Feb 2021 15:03:11
User entered 'Ondansetron'	Erynn McKinley (b) (4)	18 Feb 2021 15:02:19
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:02:19
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:38:53
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 14:00:16
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:32:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 15:02:19
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '4'	Erynn McKinley (b) (4)	18 Feb 2021 15:02:19
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	18 Feb 2021 15:02:19
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:02:19
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	18 Feb 2021 15:02:19
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:02:19
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	18 Feb 2021 15:02:19
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:02:19
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 15:02:19
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 15:02:19
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:02:19
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 15:02:19
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:02:19
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:02:19

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:02:19

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (69)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:49
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:02:19

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 10:50:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 10:50:46
Data point term sent to Coder	System	18 Feb 2021 15:04:12
User entered 'Oxycodone'	Erynn McKinley (b) (4)	18 Feb 2021 15:03:13

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:03:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 15:03:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '10'	Erynn McKinley (b) (4)	18 Feb 2021 15:03:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	18 Feb 2021 15:03:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:03:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	18 Feb 2021 15:03:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:03:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	18 Feb 2021 15:03:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:03:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:38:44
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 14:00:32
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:32:20
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 15:03:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 15:03:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:03:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 15:03:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:03:13
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:03:13

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:03:13

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (70)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:05:59
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:03:13

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 10:50:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 10:50:47
Data point term sent to Coder	System	18 Feb 2021 15:05:12
User entered 'Oxycodone'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:12

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '5'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:04:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:04:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:04:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:38:17
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 14:12:07
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:32:30
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:12

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:12
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:04:12

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:04:12

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (71)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:05
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:04:12

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 10:46:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 10:46:48
	(b) (4)	
Data point term sent to Coder	System	18 Feb 2021 15:05:12
User entered 'Pantoprazole'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:38:09
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 14:12:16
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:37:12
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '40'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:04:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:04:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:04:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:04:59
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:04:59

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:04:59

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (72)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:13
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:04:59

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 10:49:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 10:49:49
Data point term sent to Coder	System	18 Feb 2021 15:06:15
User entered 'Pantoprazole'	Erynn McKinley (b) (4)	18 Feb 2021 15:05:51

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:05:51
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:38:03
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 14:12:25
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:37:50
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 15:05:51
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '40'	Erynn McKinley (b) (4)	18 Feb 2021 15:05:51
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mg (mg)'	Erynn McKinley (b) (4)	18 Feb 2021 15:05:51
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:05:51
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	18 Feb 2021 15:05:51
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:05:51
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	18 Feb 2021 15:05:51
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:05:51
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '30 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 15:05:51
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 15:05:51
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:05:51
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '30 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 15:05:51
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:05:51
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:05:51

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:05:51

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (73)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:19
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:05:51

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	19 Mar 2021 11:36:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:36:31
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder User entered 'Phenylephrine'	System Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 15:07:16 18 Feb 2021 15:06:53

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:06:53
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 15:06:53
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '1000'	Erynn McKinley (b) (4)	18 Feb 2021 15:06:53
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	Donna Toepfer (b) (4)	03 Mar 2021 14:12:44
Signature has been broken.	Donna Toepfer (b) (4)	03 Mar 2021 14:12:44
User entered 'ug (ug)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	03 Mar 2021 14:12:44
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	18 Feb 2021 15:06:53
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User closed query 'Per DM CLR: Please review and verify if the UNIT can be appropriately recorded as ug as it is one of the pre-listed options under UNIT. If yes, please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:08:49
Query 'Per DM CLR: Please review and verify if the UNIT can be appropriately recorded as ug as it is one of the pre-listed options under UNIT. If yes, please update accordingly. ' answered with 'updated' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 14:13:03
DataPoint Un-verified.	Donna Toepfer (b) (4)	03 Mar 2021 14:12:44
Signature has been broken.	Donna Toepfer (b) (4)	03 Mar 2021 14:12:44
User entered empty; reason for change Data Entry Error	Donna Toepfer (b) (4)	03 Mar 2021 14:12:44
User opened query 'Per DM CLR: Please review and verify if the UNIT can be appropriately recorded as ug as it is one of the pre-listed options under UNIT. If yes, please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:37:50
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mcg'	Erynn McKinley (b) (4)	18 Feb 2021 15:06:53

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	18 Feb 2021 15:06:53
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:06:53
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	18 Feb 2021 15:06:53
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 15:06:53
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 15:06:53
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 15:06:53
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:06:53
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 15:06:53
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 15:06:53
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:06:53

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:06:53

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (74)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:06:29
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 15:06:53

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
	(b) (4), (b) (6)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 11:39:32
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 11:39:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 17:18:07
User entered 'Piperacillin-Tazobactam'	Erynn McKinley (b) (4)	18 Feb 2021 17:17:32
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 09:37:00
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 14:13:18
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 01:38:12
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '24'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 09:37:02
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 14:13:25
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 01:38:14
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL/hr'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '04 Nov 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (75)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:52:05
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:17:32

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTSYNONYM: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	19 Mar 2021 11:49:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:49:31
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 17:19:09
User entered 'Polyethylene Glycol'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:18:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:18:39
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:36:25
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 14:13:34
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:38:27
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 17:18:39
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '17'	Erynn McKinley (b) (4)	18 Feb 2021 17:18:39
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'g (g)'	Erynn McKinley (b) (4)	18 Feb 2021 17:18:39
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:18:39
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	18 Feb 2021 17:18:39
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:18:39
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	18 Feb 2021 17:18:39
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:18:39
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:18:39
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 17:18:39
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:18:39
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:18:39
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:18:39
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:18:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:18:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (76)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:30
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:18:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
	(b) (4), (b) (6)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 07:28:09
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 07:28:09
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 17:20:09
User entered 'Potassium Chloride'	Erynn McKinley (b) (4)	18 Feb 2021 17:19:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:19:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 17:19:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '20'	Erynn McKinley (b) (4)	18 Feb 2021 17:19:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	18 Feb 2021 17:19:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mEq'	Erynn McKinley (b) (4)	18 Feb 2021 17:19:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	18 Feb 2021 17:19:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:19:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	18 Feb 2021 17:19:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:19:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:36:46
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 14:13:43
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:38:41
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '02 Nov 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:19:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 17:19:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:19:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '06 Nov 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:19:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:19:42
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:19:42

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:19:42

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (77)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:40
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:19:42

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	25 Feb 2021 07:28:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:28:09
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 17:22:11
User entered 'Potassium Chloride'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:22:06

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:22:06
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 17:22:06
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '40'	Erynn McKinley (b) (4)	18 Feb 2021 17:22:06
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	18 Feb 2021 17:22:06
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mEq'	Erynn McKinley (b) (4)	18 Feb 2021 17:22:06
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	18 Feb 2021 17:22:06
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:22:06
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	18 Feb 2021 17:22:06
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:22:06
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:22:06
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 17:22:06
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:22:06
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '03 Nov 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:22:06
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:22:06
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:22:06

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:22:06

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (78)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:46
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:22:06

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 07:28:10
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 07:28:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 17:24:12
User entered 'Potassium Chloride'	Erynn McKinley (b) (4)	18 Feb 2021 17:23:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:23:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 17:23:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '60'	Erynn McKinley (b) (4)	18 Feb 2021 17:23:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	18 Feb 2021 17:23:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mEq'	Erynn McKinley (b) (4)	18 Feb 2021 17:23:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 18:38:23
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:05:50
DataPoint Un-verified.	Donna Toepfer (b) (4)	23 Feb 2021 22:33:08
Signature has been broken.	Donna Toepfer (b) (4)	23 Feb 2021 22:33:08
User entered 'once (ONCE)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	23 Feb 2021 22:33:08
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	19 Feb 2021 14:29:28
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	19 Feb 2021 14:29:28
User entered 'once daily (QD)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	19 Feb 2021 14:29:28
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	18 Feb 2021 17:23:30
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	18 Feb 2021 17:23:30

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:23:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Oral (ORAL)'	Erynn McKinley (b) (4)	18 Feb 2021 17:23:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:23:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:21:50
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 18:51:20
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'value is correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	11 Mar 2021 18:37:17
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 08:25:52
User signature succeeded.	Nathan Segall (b) (4)	02 Mar 2021 22:05:50
DataPoint Un-verified.	Donna Toepfer (b) (4)	23 Feb 2021 22:33:08
Signature has been broken.	Donna Toepfer (b) (4)	23 Feb 2021 22:33:08
User entered '29 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	23 Feb 2021 22:33:08
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:23:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 17:23:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:23:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:23:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:23:30
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
User entered empty.	System	23 Feb 2021 22:33:08
User entered '1'	System	19 Feb 2021 14:29:28
User entered empty.	System	18 Feb 2021 17:23:30

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
User entered empty.	System	23 Feb 2021 22:33:08
User entered '1'	System	19 Feb 2021 14:29:28
User entered empty.	System	18 Feb 2021 17:23:30

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (79)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:07:53
	(b) (4), (b) (6)	
User entered empty.	System	23 Feb 2021 22:33:08
User entered '804 (804)'	System	19 Feb 2021 14:29:28
User entered empty.	System	18 Feb 2021 17:23:30

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
	(b) (4), (b) (6)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 09:12:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 09:12:37
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 07:28:08
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 07:28:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 17:25:13
User entered 'Potassium Chloride'	Erynn McKinley (b) (4)	18 Feb 2021 17:24:39
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '20'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mEq'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '01 Nov 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (80)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:10
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:24:39

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	05 Mar 2021 05:33:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:33:47
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder User entered 'Propofol'	System Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:26:13 18 Feb 2021 17:25:41

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:25:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 17:25:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:35:58
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 14:14:14
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:39:02
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Sliding Scale'	Erynn McKinley (b) (4)	18 Feb 2021 17:25:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	18 Feb 2021 17:25:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL/hr'	Erynn McKinley (b) (4)	18 Feb 2021 17:25:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	18 Feb 2021 17:25:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:25:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	18 Feb 2021 17:25:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:25:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:25:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 17:25:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:25:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:25:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:25:41
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:25:41

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:25:41

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (81)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:07
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:25:41

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
	(b) (4), (b) (6)	
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)	19 Apr 2021 10:08:30
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 10:08:30
	(b) (4)	
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)	15 Mar 2021 15:19:58
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 15:19:58
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 17:27:14
Data point term sent to Coder	System	18 Feb 2021 17:26:14
User entered 'Sodium Bicarbonate'	Erynn McKinley (b) (4)	18 Feb 2021 17:25:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:26:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 17:26:50
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:26:50
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:25:57
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:26:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 17:26:50
User entered 'Worsening Aortic Aneurysm' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:26:50
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:25:57
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:26:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 17:26:50
User entered '50' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:26:50
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:25:57
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:26:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 17:26:50
User entered 'Other (OTHER)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:26:50
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:25:57
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mEq' reason for change: Data Entry Error	Erynn McKinley (b) (4)	18 Feb 2021 17:26:50
User entered empty.	(b) (4)	
	Erynn McKinley (b) (4)	18 Feb 2021 17:25:57
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:26:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 17:26:50
User entered 'as needed (PRN)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:26:50
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:25:57
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:26:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 17:26:50
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:26:50
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:25:57
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	18 Feb 2021 17:26:50
User entered '28 Oct 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:26:50
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	18 Feb 2021 17:25:57
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:26:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 17:26:50
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:26:50
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:25:57
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020' reason for change: Data Entry Error	Erynn McKinley (b) (4)	18 Feb 2021 17:26:50
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:26:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Feb 2021 17:26:50
User entered 'No (N)' reason for change: Data Entry Error	Erynn McKinley (b) (4)	18 Feb 2021 17:26:50
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Feb 2021 17:25:57
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (82)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:14
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:25:57

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: SODIUM BICARBONATE - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6) 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
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 17:28:14
User entered 'Sodium Bicarbonate'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:28:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:28:10
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 17:28:10
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '50'	Erynn McKinley (b) (4)	18 Feb 2021 17:28:10
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	18 Feb 2021 17:28:10
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mEq'	Erynn McKinley (b) (4)	18 Feb 2021 17:28:10
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	18 Feb 2021 17:28:10
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:28:10
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	18 Feb 2021 17:28:10
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Epidural'	Erynn McKinley (b) (4)	18 Feb 2021 17:28:10
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:28:10
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 17:28:10
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:28:10
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:28:10
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:28:10
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:28:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:28:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (83)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:15
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:28:10

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
	(b) (4), (b) (6)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 14:03:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 14:03:47
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 08:36:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 08:36:52
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: IRRIGATING SOLUTIONS, ATC: SALT SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 00:17:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Mar 2021 00:17:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 17:30:18
User entered 'Sodium Chloride'	Erynn McKinley (b) (4)	18 Feb 2021 17:29:24
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '2000'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL (mL)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'once (ONCE)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 09:35:35
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 14:14:31
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 01:40:36
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Irrigation'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (84)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:02:42
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:29:24

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
	(b) (4), (b) (6)	
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 PHOSPHATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 10:14:35
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 10:14:35
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 17:31:18
User entered 'Sodium Phosphate 20 mmol in Dextrose'	Erynn McKinley (b) (4)	18 Feb 2021 17:30:50
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '62.5'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL/hr'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'once (ONCE)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Mar 2021 09:35:11
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 14:15:46
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 01:40:54
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (85)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:01:41
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:30:50

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
	(b) (4), (b) (6)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 17:42:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 17:42:28
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 17:32:19
User entered 'Vancomycin'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:32:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:32:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:34:36
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 14:16:25
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:41:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 17:32:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'I'	Erynn McKinley (b) (4)	18 Feb 2021 17:32:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'g (g)'	Erynn McKinley (b) (4)	18 Feb 2021 17:32:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:32:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'once (ONCE)'	Erynn McKinley (b) (4)	18 Feb 2021 17:32:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:32:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	18 Feb 2021 17:32:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:34:50
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'correct per hospital records' (Site from DM).	Donna Toepfer (b) (4)	03 Mar 2021 14:16:41
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 01:41:57
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Implant/Chest'	Erynn McKinley (b) (4)	18 Feb 2021 17:32:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:32:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 17:32:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:32:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:32:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:32:04
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:32:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:32:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (86)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:33
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:32:04

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
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.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	28 Feb 2021 17:18:27
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 17:18:27
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
Data point term sent to Coder	System	18 Feb 2021 17:33:20
User entered 'Vasopressin in Sodium Chloride'	Erynn McKinley (b) (4) (b) (4)	18 Feb 2021 17:33:08

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:33:08
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Worsening Aortic Aneurysm'	Erynn McKinley (b) (4)	18 Feb 2021 17:33:08
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Sliding Scale'	Erynn McKinley (b) (4)	18 Feb 2021 17:33:08
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Other (OTHER)'	Erynn McKinley (b) (4)	18 Feb 2021 17:33:08
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'mL/hr'	Erynn McKinley (b) (4)	18 Feb 2021 17:33:08
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'as needed (PRN)'	Erynn McKinley (b) (4)	18 Feb 2021 17:33:08
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:33:08
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'Intravenous (INTRAVENOUS)'	Erynn McKinley (b) (4)	18 Feb 2021 17:33:08
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered empty.	Erynn McKinley (b) (4)	18 Feb 2021 17:33:08
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '28 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:33:08
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '0'	Erynn McKinley (b) (4)	18 Feb 2021 17:33:08
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:33:08
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered '29 Oct 2020'	Erynn McKinley (b) (4)	18 Feb 2021 17:33:08
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 15:03:53
User signature succeeded.	Nathan Segall (b) (4)	19 Feb 2021 14:52:31
User entered 'No (N)'	Erynn McKinley (b) (4)	18 Feb 2021 17:33:08
	(b) (4)	

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:33:08

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:33:08

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (87)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:40
User entered empty.	(b) (4), (b) (6) System	18 Feb 2021 17:33:08

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Mar 2021 15:03:56
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	15 Mar 2021 15:03:56
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	15 Mar 2021 15:03:07
User entered 'Acetaminophen'	Donna Toepfer (b) (4)	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User entered 'Worsening aortic aneurysm'	Donna Toepfer (b) (4)	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User entered '1000'	Donna Toepfer (b) (4)	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User entered 'mg (mg)'	Donna Toepfer (b) (4)	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User entered empty.	Donna Toepfer (b) (4)	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User entered 'as needed (PRN)'	Donna Toepfer (b) (4)	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User entered empty.	Donna Toepfer (b) (4)	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User entered 'Intravenous (INTRAVENOUS)'	Donna Toepfer (b) (4)	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User entered empty.	Donna Toepfer (b) (4)	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	15 Mar 2021 15:02:32
User entered '28 Oct 2020' reason for change: Data Entry Error	Donna Toepfer (b) (4)	15 Mar 2021 15:02:32
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	15 Mar 2021 15:02:23
User entered empty.	Donna Toepfer (b) (4)	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User entered '0'	Donna Toepfer (b) (4)	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User entered '28 Oct 2020'	Donna Toepfer (b) (4)	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	22 Mar 2021 15:04:23
User signature succeeded.	Nathan Segall (b) (4)	15 Mar 2021 16:05:31
User entered 'No (N)'	Donna Toepfer (b) (4)	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (88)

Generated On: 09 Jun 2021 16:11:06

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 17:08:47
User entered empty.	(b) (4), (b) (6) System	15 Mar 2021 15:02:23

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:11:06

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:33:24
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:52:33
DataPoint Un-verified.	Donna Toepfer (b) (4)	17 Nov 2020 21:16:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Donna Toepfer (b) (4)	17 Nov 2020 21:16:25
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:56:47
User entered 'No (N)'	Donna Toepfer (b) (4)	11 Sep 2020 18:58:08

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:11:06

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:53:11
User entered '09 Oct 2020'	Donna Toepfer (b) (4)	17 Nov 2020 21:17:06

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:11:06

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:53:11
User entered 'Cardiac Catheterization'	Donna Toepfer (b) (4)	17 Nov 2020 21:17:06

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:53:11
User entered 'Adverse Event (AE)'	Donna Toepfer (b) (4)	17 Nov 2020 21:17:06

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:11:06

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:53:11
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:17:06

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:06

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:12:55
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:53:11
User entered '28 Oct 2020'	Donna Toepfer (b) (4)	17 Nov 2020 21:18:38

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:06

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:12:55
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:53:11
User entered '1-V CORONARY ARTERY BYPASS GRAFT' reason for change: Data Entry Error	Donna Toepfer (b) (4)	09 Dec 2020 21:42:51
User entered 'Coronary Artery Bypass Graft'	Donna Toepfer (b) (4)	17 Nov 2020 21:18:38

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:12:55
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:53:11
User entered 'Adverse Event (AE)'	Donna Toepfer (b) (4)	17 Nov 2020 21:18:38

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:11:06

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:12:55
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:53:11
User entered empty.	Donna Toepfer (b) (4)	17 Nov 2020 21:18:38

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:11:06

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:12:59
User closed query 'According to hospital records, the subject had an Echocardiogram on 09JAN2020. Please review these records in source and add Echocardiogram as required ? ' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 15:28:37
Query 'According to hospital records, the subject had an Echocardiogram on 09JAN2020. Please review these records in source and add Echocardiogram as required ? ' answered with 'this is prior to consent' (Site from CRA).	Donna Toepfer (b) (4)	17 Feb 2021 22:27:12
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 16:07:13
User opened query 'According to hospital records, the subject had an Echocardiogram on 09JAN2020. Please review these records in source and add Echocardiogram as required ? ' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 16:06:45
User closed query 'According to hospital records, the subject had an Echocardiogram on 09JAN2020. Please review these records in source and add Echocardiogram as required' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 16:06:45
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
Query 'According to hospital records, the subject had an Echocardiogram on 09JAN2020. Please review these records in source and add Echocardiogram as required' answered with 'procedures before and after hospitalization are only added to edc' (Site from CRA).	Donna Toepfer (b) (4)	10 Feb 2021 15:45:20
User opened query 'According to hospital records, the subject had an Echocardiogram on 09JAN2020. Please review these records in source and add Echocardiogram as required' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:17:49
User closed query 'According to hospital records, the subject had an Echocardiogram on 09JAN2020. Please review these records in source and add Echocardiogram as required.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:17:35

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:11:06

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'According to hospital records, the subject had an Echocardiogram on 09JAN2020. Please review these records in source and add Echocardiogram as required.' answered with 'hospital procedures not added in edc' (Site from CRA). DataPoint Un-verified.	Donna Toepfer (b) (4) [REDACTED] [REDACTED]	30 Jan 2021 16:36:37
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	27 Jan 2021 16:53:37
User opened query 'According to hospital records, the subject had an Echocardiogram on 09JAN2020. Please review these records in source and add Echocardiogram as required.' (Site from CRA). User entered '28 Oct 2020'	(b) (4), (b) (6) [REDACTED] Donna Toepfer (b) (4) [REDACTED] [REDACTED]	27 Jan 2021 16:53:11 27 Jan 2021 16:49:40 09 Dec 2020 21:42:21

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:11:06

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:12:59
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:53:11
User entered 'Ascending Aortic Replacement'	Donna Toepfer (b) (4)	09 Dec 2020 21:42:21

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:11:06

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:12:59
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:53:11
User entered 'Adverse Event (AE)'	Donna Toepfer (b) (4)	09 Dec 2020 21:42:21

US3242231

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:11:06

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:12:59
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:53:11
User entered empty.	Donna Toepfer (b) (4)	09 Dec 2020 21:42:21

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'USA-US067-2020-MRNA-1273-P301000003'	System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'Yes (Y)'	System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'No (N)'	System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:35:10
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	System	05 Mar 2021 18:36:43
Signature has been broken.	System	05 Mar 2021 18:36:43
User entered 'Nathan'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Un-reviewed for Safety.	System	22 Sep 2020 15:35:04
User entered empty.	System	22 Sep 2020 15:35:04
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
Amendment Manager: User entered 'Nathan'	System	14 Sep 2020 22:09:40

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:46:57
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	System	05 Mar 2021 18:36:43
Signature has been broken.	System	05 Mar 2021 18:36:43
User entered 'Segall'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Un-reviewed for Safety.	System	22 Sep 2020 15:35:04
User entered empty.	System	22 Sep 2020 15:35:04
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
Amendment Manager: User entered 'Segall'	System	14 Sep 2020 22:09:40

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:46:55
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	System	05 Mar 2021 18:36:43
Signature has been broken.	System	05 Mar 2021 18:36:43
User entered '175 country club dr st100a'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Un-reviewed for Safety.	System	22 Sep 2020 15:35:04
User entered empty.	System	22 Sep 2020 15:35:04
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
Amendment Manager: User entered '175 country club dr st100a'	System	14 Sep 2020 22:09:40

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:46:53
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	System	05 Mar 2021 18:36:43
Signature has been broken.	System	05 Mar 2021 18:36:43
User entered 'Stockbridge'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Un-reviewed for Safety.	System	22 Sep 2020 15:35:04
User entered empty.	System	22 Sep 2020 15:35:04
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
	(b) (4), (b) (6)	
Amendment Manager: User entered 'Stockbridge'	System	14 Sep 2020 22:09:40

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 13:35:36
User closed query 'Please enter the state of site address' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 13:35:24
Query 'Please enter the state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 15:00:57
User entered 'GA'	Donna Toepfer (b) (4)	16 Apr 2021 15:00:40
User opened query 'Please enter the state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:47:15

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:35:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	System	05 Mar 2021 18:36:43
Signature has been broken.	System	05 Mar 2021 18:36:43
User entered '30281'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Un-reviewed for Safety.	System	22 Sep 2020 15:35:04
User entered empty.	System	22 Sep 2020 15:35:04
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
	(b) (4), (b) (6)	
Amendment Manager: User entered '30281'	System	14 Sep 2020 22:09:40

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Sep 2020 15:34:53
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:12:31
User entered 'US' (non-conformant).	System	12 Sep 2020 19:08:21

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
	(b) (4)	
User entered '2'	System	22 Sep 2020 15:35:04
User entered '1'	System	12 Sep 2020 19:08:21

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'USA-US067-2020-MRNA-1273-P301000003'	System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:35:10
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	System	05 Mar 2021 18:36:43
Signature has been broken.	System	05 Mar 2021 18:36:43
User entered 'Nathan'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Un-reviewed for Safety.	System	22 Sep 2020 15:35:04
User entered empty.	System	22 Sep 2020 15:35:04
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
	(b) (4), (b) (6)	
Amendment Manager: User entered 'Nathan'	System	14 Sep 2020 22:09:40

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:46:57
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	System	05 Mar 2021 18:36:43
Signature has been broken.	System	05 Mar 2021 18:36:43
User entered 'Segall'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Un-reviewed for Safety.	System	22 Sep 2020 15:35:04
User entered empty.	System	22 Sep 2020 15:35:04
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
	(b) (4), (b) (6)	
Amendment Manager: User entered 'Segall'	System	14 Sep 2020 22:09:40

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:46:55
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	System	05 Mar 2021 18:36:43
Signature has been broken.	System	05 Mar 2021 18:36:43
User entered '175 country club dr st100a'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Un-reviewed for Safety.	System	22 Sep 2020 15:35:04
User entered empty.	System	22 Sep 2020 15:35:04
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
	(b) (4), (b) (6)	
Amendment Manager: User entered '175 country club dr st100a'	System	14 Sep 2020 22:09:40

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:46:53
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	System	05 Mar 2021 18:36:43
Signature has been broken.	System	05 Mar 2021 18:36:43
User entered 'Stockbridge'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Un-reviewed for Safety.	System	22 Sep 2020 15:35:04
User entered empty.	System	22 Sep 2020 15:35:04
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
	(b) (4), (b) (6)	
Amendment Manager: User entered 'Stockbridge'	System	14 Sep 2020 22:09:40

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 13:35:36
User closed query 'Please enter the state of site address' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 13:35:24
Query 'Please enter the state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 15:00:57
User entered 'GA'	Donna Toepfer (b) (4)	16 Apr 2021 15:00:40
User opened query 'Please enter the state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:47:15

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:35:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	System	05 Mar 2021 18:36:43
Signature has been broken.	System	05 Mar 2021 18:36:43
User entered '30281'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Un-reviewed for Safety.	System	22 Sep 2020 15:35:04
User entered empty.	System	22 Sep 2020 15:35:04
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
	(b) (4), (b) (6)	
Amendment Manager: User entered '30281'	System	14 Sep 2020 22:09:40

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Sep 2020 15:34:53
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:12:31
User entered 'US' (non-conformant).	System	12 Sep 2020 19:08:21

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
	(b) (4)	
User entered '2'	System	22 Sep 2020 15:35:04
User entered '1'	System	12 Sep 2020 19:08:21

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:11:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
User entered '12/Sep/2020 15:08'	System	12 Sep 2020 19:08:21

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:11:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	22 Sep 2020 15:34:53
User entered 'I'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Sep 2020 19:08:21

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'USA-US067-2020-MRNA-1273-P301000003'	System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'Yes (Y)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:08:15
User entered 'No (N)'	(b) (4), (b) (6) System	12 Sep 2020 18:58:27

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:35:10
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	System	05 Mar 2021 18:36:43
Signature has been broken.	System	05 Mar 2021 18:36:43
User entered 'Nathan'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Un-reviewed for Safety.	System	22 Sep 2020 15:35:04
User entered empty.	System	22 Sep 2020 15:35:04
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
	(b) (4), (b) (6)	
Amendment Manager: User entered 'Nathan'	System	14 Sep 2020 22:09:40

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:46:57
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	System	05 Mar 2021 18:36:43
Signature has been broken.	System	05 Mar 2021 18:36:43
User entered 'Segall'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Un-reviewed for Safety.	System	22 Sep 2020 15:35:04
User entered empty.	System	22 Sep 2020 15:35:04
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
	(b) (4), (b) (6)	
Amendment Manager: User entered 'Segall'	System	14 Sep 2020 22:09:40

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:46:55
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	System	05 Mar 2021 18:36:43
Signature has been broken.	System	05 Mar 2021 18:36:43
User entered '175 country club dr st100a'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Un-reviewed for Safety.	System	22 Sep 2020 15:35:04
User entered empty.	System	22 Sep 2020 15:35:04
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
	(b) (4), (b) (6)	
Amendment Manager: User entered '175 country club dr st100a'	System	14 Sep 2020 22:09:40

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:46:53
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	System	05 Mar 2021 18:36:43
Signature has been broken.	System	05 Mar 2021 18:36:43
User entered 'Stockbridge'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Un-reviewed for Safety.	System	22 Sep 2020 15:35:04
User entered empty.	System	22 Sep 2020 15:35:04
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
	(b) (4), (b) (6)	
Amendment Manager: User entered 'Stockbridge'	System	14 Sep 2020 22:09:40

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 13:35:36
User closed query 'Please enter the state of site address' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 13:35:24
Query 'Please enter the state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 15:00:57
User entered 'GA'	Donna Toepfer (b) (4)	16 Apr 2021 15:00:40
User opened query 'Please enter the state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:47:15

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:35:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
DataPoint Un-verified.	System	05 Mar 2021 18:36:43
Signature has been broken.	System	05 Mar 2021 18:36:43
User entered '30281'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Un-reviewed for Safety.	System	22 Sep 2020 15:35:04
User entered empty.	System	22 Sep 2020 15:35:04
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
	(b) (4), (b) (6)	
Amendment Manager: User entered '30281'	System	14 Sep 2020 22:09:40

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 15:34:53
	(b) (4), (b) (6)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:12:31
User entered 'US' (non-conformant).	System	12 Sep 2020 19:08:21

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
	(b) (4)	
User entered '2'	System	22 Sep 2020 15:35:04
User entered '1'	System	12 Sep 2020 19:08:21

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:11:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
User entered '22/Sep/2020 11:35'	System	22 Sep 2020 15:35:04

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:11:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:57:36
User entered 'I'	(b) (4), (b) (6) (b) (4), (b) (6)	22 Sep 2020 15:35:04

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'USA-US067-2020-MRNA-1273-P301000013'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'Yes (Y)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'Yes (Y)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered 'Nathan'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered 'Segall'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:45
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered '175 country club dr st100a'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered 'Stockbridge'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 13:37:53
User closed query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 13:37:35
Query 'Please enter state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 15:01:45
User entered 'GA'	Donna Toepfer (b) (4)	16 Apr 2021 15:01:26
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:48:08

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:48:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered '30281'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:36:01
User entered 'US'	System	18 Nov 2020 14:18:23

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
	(b) (4)	
User entered '3'	System	10 Dec 2020 17:26:50
User entered '2'	System	02 Dec 2020 14:36:15
User entered '1'	System	18 Nov 2020 14:18:23

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'USA-US067-2020-MRNA-1273-P301000013'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'Yes (Y)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Death

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'Yes (Y)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered 'Nathan'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered 'Segall'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:45
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered '175 country club dr st100a'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered 'Stockbridge'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 13:37:53
User closed query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 13:37:35
Query 'Please enter state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 15:01:45
User entered 'GA'	Donna Toepfer (b) (4)	16 Apr 2021 15:01:26
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:48:08

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:48:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered '30281'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:36:01
User entered 'US'	System	18 Nov 2020 14:18:23

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
	(b) (4)	
User entered '3'	System	10 Dec 2020 17:26:50
User entered '2'	System	02 Dec 2020 14:36:15
User entered '1'	System	18 Nov 2020 14:18:23

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:11:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
User entered '18/Nov/2020 09:18'	System	18 Nov 2020 14:18:23

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:11:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:36:01
User entered 'I'	(b) (4), (b) (6)	18 Nov 2020 14:18:23

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'USA-US067-2020-MRNA-1273-P301000013'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'Yes (Y)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'Yes (Y)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered 'Nathan'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered 'Segall'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:45
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered '175 country club dr st100a'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered 'Stockbridge'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 13:37:53
User closed query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 13:37:35
Query 'Please enter state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 15:01:45
User entered 'GA'	Donna Toepfer (b) (4)	16 Apr 2021 15:01:26
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:48:08

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:48:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered '30281'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:36:01
User entered 'US'	System	18 Nov 2020 14:18:23

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
	(b) (4)	
User entered '3'	System	10 Dec 2020 17:26:50
User entered '2'	System	02 Dec 2020 14:36:15
User entered '1'	System	18 Nov 2020 14:18:23

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:11:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
User entered '02/Dec/2020 14:36'	System	02 Dec 2020 14:36:15

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:11:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
User entered 'I'	(b) (4), (b) (6)	02 Dec 2020 14:36:15

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'USA-US067-2020-MRNA-1273-P301000013'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'Yes (Y)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'Yes (Y)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered 'Nathan'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered 'Segall'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:45
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered '175 country club dr st100a'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered 'Stockbridge'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 13:37:53
User closed query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 13:37:35
Query 'Please enter state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 15:01:45
User entered 'GA'	Donna Toepfer (b) (4)	16 Apr 2021 15:01:26
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:48:08

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:48:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered '30281'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:36:01
User entered 'US'	System	18 Nov 2020 14:18:23

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
	(b) (4)	
User entered '3'	System	10 Dec 2020 17:26:50
User entered '2'	System	02 Dec 2020 14:36:15
User entered '1'	System	18 Nov 2020 14:18:23

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:11:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
User entered '10/Dec/2020 11:26'	System	10 Dec 2020 17:26:50

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:11:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
User entered 'I'	(b) (4), (b) (6)	10 Dec 2020 17:26:50

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'USA-US067-2020-MRNA-1273-P301000013'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Serious

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'Yes (Y)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'Yes (Y)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:18:14
User entered 'No (N)'	System	18 Nov 2020 14:17:11

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:41
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered 'Nathan'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:43
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered 'Segall'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:45
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered '175 country club dr st100a'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:47:47
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered 'Stockbridge'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Jon Finley (b) (4)	20 Apr 2021 21:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 13:37:53
User closed query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 13:37:35
Query 'Please enter state of site address' answered with 'updated' (Site from CRA).	Donna Toepfer (b) (4)	16 Apr 2021 15:01:45
User entered 'GA'	Donna Toepfer (b) (4)	16 Apr 2021 15:01:26
User opened query 'Please enter state of site address' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 03:48:08

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:48:28
	(b) (4), (b) (6)	
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
User entered '30281'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	10 Feb 2021 20:11:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 16:51:04
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 14:36:01
User entered 'US'	System	18 Nov 2020 14:18:23

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:11:06

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Mar 2021 18:36:43
User signature succeeded.	Nathan Segall (b) (4)	10 Feb 2021 20:11:47
	(b) (4)	
User entered '3'	System	10 Dec 2020 17:26:50
User entered '2'	System	02 Dec 2020 14:36:15
User entered '1'	System	18 Nov 2020 14:18:23

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:11:06

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4)	06 Mar 2021 14:44:58
	(b) (4)	
User entered '05/Mar/2021 10:36'	System	05 Mar 2021 18:36:43

US3242231

Folder: SAE USA-US067-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:11:06

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Nathan Segall (b) (4) (b) (4)	06 Mar 2021 14:44:58
User entered 'I'	(b) (4), (b) (6)	05 Mar 2021 18:36:43